

A large, stylized yellow map of Japan is positioned in the background, showing the four main islands: Hokkaido, Honshu, Shikoku, and Kyushu.

The Fourth Arrow

The EBC Report on the Japanese Business Environment 2013

**The European Business Council in Japan,
The European (EU) Chamber of Commerce in Japan**

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European Business Council in Japan European (EU) Chamber of Commerce in Japan

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The European Business Council (EBC) is the trade policy arm of the 17 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents some 2,500 local European companies and individuals who are members of their national chambers of commerce. Around 350 company executives participate directly in the EBC's 30 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

The EBC speaks from a platform based on member consensus, representing the common view of companies from a major economic region in the world and one of Japan's most important trading partners.

The EBC works closely with the Delegation of the European Union in Japan and the embassies of European countries to co-ordinate policy proposals and facilitate European business in Japan.

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Message from the Chairman

Welcome to the 2013 EBC Report on the Japanese business environment. There have been many significant developments since our report of last year. Prime Minister Abe, who came into office in December 2012, swiftly announced plans for achieving long-term, sustainable economic growth based on three pillars or “arrows” of activity, comprising monetary policy, fiscal stimulus and structural reform. The Prime Minister has recognised the importance of trade to the achievement of his plans. His Government has signed up to the negotiations towards the Trans Pacific Partnership (TPP) and, on 25th March this year, joined the European Union in announcing the launch of negotiations towards an EU-Japan Free Trade Agreement/Economic Partnership Agreement (FTA/EPA).

The purpose of this report is to help support the next phase of negotiations. It reminds us of the key challenges facing European businesses in Japan, whether these relate to tariff or non-tariff barriers, both of which work against the interests of government, business, and consumers. There is no doubt that companies face unnecessary difficulties in this market, not least the labyrinthine administrative practices, unique Japanese standards, and protracted product approval and certification processes. This report covers the most important issues, with proposals for how they should be addressed.

The core mission of the EBC is to promote an impediment-free business and investment environment in Japan that will make it less difficult and costly to do business here. The advantages to Japan are obvious – an impediment-free market will serve as a catalyst for global trade liberalisation and prosperity. Unified markets are needed to create a business environment that will stimulate innovation and economic growth, leading to more investment and creating new jobs. These are the very same benefits that will flow to the EU if an optimal conclusion of mutually beneficial negotiations is achieved, thereby ensuring that the EU and Japan continue to play leading roles in shaping the future of the global economy.

Surprisingly, the importance of Japan to the EU, and vice versa, is occasionally questioned. Although this would seem to be self-evident, it is worth re-emphasising how essential this relationship is. The EU and Japan account together for nearly one-third of global GDP. What makes the relationship so uniquely important is that whilst our two regions contribute so significantly to the global economy, stability, and culture, there is at the same time a huge underperformance in mutual trade, investment and collaboration; it could be so much better. For example, Japan is only the EU’s 6th largest export market, following the US, Switzerland, China, Russia, and Turkey, in that order, and coming only just ahead of Norway. Deep down, the leadership of both regions understand their mutual importance, and regret the missed opportunities. Now is the time to put this right.

I wish to personally thank all of our sector committee members and chairmen, who are the backbone of the EBC, the European National Chambers of Commerce, whose support is essential, the European Commission, the Delegation of the EU to Japan, the European national Embassies in Japan, as well as members of the Japanese Government, associations and industry, all of with whom our relationships have steadily flourished over the years, to the point where we can speak of a true collaborative spirit.

This report is entitled *The Fourth Arrow*. Implementation of its recommendations will contribute significantly to Prime Minister Abe’s third arrow of reform. We hope it can serve as a useful tool and reference source for everyone involved in the growth of the EU-Japan economic relationship, and in the successful conclusion of the EU-Japan FTA/EPA, helping to ensure the future vitality of our regions in an increasingly competitive and challenging world.

Duco Delgorge
Chairman
European Business Council in Japan
The European (EU) Chamber of Commerce in Japan
(President, MIE PROJECT Co., Ltd.)

Message from the Executive Director

The European Business Council in Japan (EBC) is pleased to present its 2013 Report on the Japanese Business Environment: *The Fourth Arrow*.

This is an exciting time to be in Japan: there are signs of economic recovery, the Government of Japan seems determined to set the country on a path of long-term growth, it has ambitious plans to reform many of the structures and regulations that have in the past resisted change, and there is an openness to new and enhanced trade relationships. So we have some grounds to be optimistic. On the other hand, it is too early to say whether such glimpses of progress will translate into sustainable results: the real test of the vision, ambition, and announcements is yet to come.

The EBC is taking a particularly close interest in progress towards a Free Trade Agreement/Economic Partnership Agreement between the European Union and Japan. Negotiations were launched in April 2013 and are now approaching their first anniversary and a critical progress review. Unlocking the full potential of the EU-Japan trade relationship to contribute to economic growth depends on both sides remaining completely committed to the roadmap for the negotiations and ensuring they remain on track. The EBC is doing all it can to support this process and trusts that this report will contribute to an understanding on both sides of what needs to be achieved.

Specifically, the aim of this report is to offer recommendations for how the Government of Japan should reform the business environment so that it better serves the respective interests of the business community, consumers, other stakeholders and the overall economy. The EBC is fortunate to have 30 sector committee chairmen and over 350 committee members whose enthusiasm and efforts are the driving force of the EBC. Without the knowledge and experience of these dedicated people, it would not have been possible to produce this report. Our recommendations are based on the insights of the EBC's sectoral committees and reflect their considerable expertise and experience gained in Japan and other markets. We are indebted to them for their valued expertise, as well as to our Committee Chairmen, many member companies, and stakeholders. Finally, it is thanks to the EBC Policy Director, Bjorn Kongstad, and his tireless efforts to collect, coordinate and combine so many contributions that the report exists at all.

On behalf of the EBC, I would like to acknowledge the vital role of the Delegation of the European Union to Japan and the European national embassies in Tokyo as supporters of our work. Last but by no means least, I am grateful to all the EBC Members whose financial support has made this publication possible and whose generosity is acknowledged in the sponsors and supporters sections at the end of the report.

There seems little doubt that Japan is at a turning point. The Government of Japan has launched its plan for returning the economy to sustainable growth and started the long process of implementation, recognising the important contribution of trade to its success. The many concrete recommendations in this report can help the Government focus its efforts where they are most needed and secure early, tangible progress. We therefore commend the report to the Government as a "Fourth Arrow" offering recommendations that the Prime Minister's "Third Arrow" of structural reform appears to lack, and we look forward to opportunities to discuss our recommendations in further detail.

Alison Murray
Executive Director
European Business Council in Japan
The European (EU) Chamber of Commerce in Japan



Introduction



INTRODUCTION

Can it really be less than a year since Japan was introduced to Abenomics? The term has become so firmly fixed in the lexicon that it is easy to forget its novelty. Ever since Shinzo Abe, Prime Minister of Japan since December 2012, announced his grand economic plan to force Japan out of deflation and recession, the country and markets have been transfixed with the question: will it work?

Abenomics is a combination of aggressive measures across three key areas or “arrows”: monetary policy, fiscal stimulus and structural reform. However, the real action so far has been confined to the first two. The Bank of Japan has been persuaded to try to end deflation by expanding Japan's money supply through purchases of Japanese government bonds and other assets, and to double its inflation target to two per cent. The Government has started pumping money into stimulus measures, including major infrastructure projects, scientific research and renewable energy. Consumption tax is to rise to cover some of the Government's increased debt exposure, but meanwhile employers are being asked to implement wage increases to ensure consumer spending does not fall. Early actions were quick to yield results: the yen fell dramatically against the dollar, euro and other currencies; exports and export profits rose; share prices boomed; the economy grew at an annualised rate of 3.5 percent in the first quarter. Abenomics was off to a flying start. The hope is that the economy might enter a "virtuous cycle" of rising prices, rising wages and rising demand. Yet there is also a risk that, by boosting exports, the weaker yen could allow Japanese industry to put off much needed productivity improvements; and that ill-conceived government spending on infrastructure could sap competitiveness and distract attention from much needed restructuring.

Boosting productivity will be crucial to the success of Abenomics, but depends greatly on the willingness of enterprises to adopt new policies and practices and, at the macro level, of policy-makers to meet the challenge of a population in seemingly permanent decline, predicted to fall from around 127 million today to around 107 million by 2040. These figures reflect both a low birth rate and no net immigration. Moreover, with one of the highest life expectancies in the world, the proportion of older people (aged 65 and over) in the dwindling population is set to reach some 30 percent by 2040.

The realisation is, therefore, dawning that much of the success of Abenomics hangs on its third arrow: structural reform, which was presented with much fanfare. Yet, just a few months after the first reform policies were made public, many are beginning to doubt whether they will be adequate. There are concerns that some of the third arrow strategies will lead only to insignificant growth, while failing to deal with critical problems in the relevant infrastructure. One example is the goal of promoting medical tourism, which will not in any way address the complex administrative practices, unique Japanese standards, and protracted product approval and certification processes faced by companies attempting to bring state-of-the-art pharmaceuticals, medical diagnostics and medical equipment to the Japanese market and hence to Japanese patients. Another example is Japan's goal of developing the world's best quality agricultural products. While the quality of Japanese farm products is not in doubt, it is not an understatement to say that Japan's agricultural sector overall is not competitive on the global market. Amongst other proposals are measures aiming to stimulate capital investment, create special economic zones, increase the participation of women in the workforce, overhaul education, and liberalise the power supply market, all of which could be effective, but the Government has been slow to offer detail of how these goals will be achieved.

No surprise then that Prime Minister Abe's proposals for structural reform have met with great scrutiny and interest. To be frank, in many respects they differ little from previous growth strategies, but combined with other current initiatives and the support the Government enjoys in both houses of the Parliament, they offer some hope of a step change in the economy. The EBC particularly appreciates the recognition of the importance of international trade and investment to future growth. The Government of Japan has indicated it wants to increase the level of trade conducted under the umbrella of free trade agreements from the current 19 percent to some 70 percent by 2018. A decision was made early in 2013 that Japan should join the negotiations towards a Trans Pacific Partnership and this was followed, in April 2013, by a joint announcement with the European Union on the immediate launch of negotiations towards a mutual free trade agreement/economic partnership agreement (FTA/EPA).



The case for an ambitious, comprehensive, and mutually beneficial EU-Japan FTA/EPA is clear - Japan is the EU's seventh largest trading partner and the EU ranks as Japan's third largest trading partner. While already significant, this trade relationship has considerable upwards potential. The benefits would stretch beyond the many European and Japanese companies already operating in each other's home markets to all those, current and future, seeking to expand in this way. The EBC supports the FTA/EPA negotiations, but insists that any deal must address the specific concerns of European business in Japan, reflected in this and previous reports. With so much at stake, we are urging the authorities on both sides to ensure that the necessary progress is made.

Many reforms are required to secure a fair and competitive environment for European business. These reforms have been identified by EBC Committees based on the extensive first-hand operational experience of their members in Japan and in many other markets. The report sets out in detail their findings, with concrete recommendations for how each issue should be addressed. The recommendations include:

- Mutual recognition of standards, product certifications and marketing authorisations, and adoption of international standards, for example in terms of medical equipment, environmental technology, consumer products, cars, and food.
- Lifting of barriers, such as high costs and unnecessary bureaucracy that prevent or delay products from reaching the market – for example, in terms of tariffs on certain foods, and Japan-only product labelling requirements.
- Ensuring fair competition and fair and equal treatment of all companies, domestic and foreign, for example in the airline and insurance sectors.
- Ensuring fairer and more open competition in services – which would mean, for example, introducing truly open tendering for public procurement contracts, and improved network access for foreign telecom carriers.
- Improving conditions for foreign direct investment, including requirements unique to Japan in the banking and asset management sectors. And finally,
- Enhancing incentives for investment in R&D, including reimbursement schemes in the healthcare sector that recognise and reward innovation.

Achieving a fairer, more competitive business environment in Japan is not only in the interest of European firms here, but would also contribute significantly to the key objective of Abenomics, to achieve long-term sustainable economic growth. The specificity and pragmatism of the EBC's recommendations complement the broad ambitions of the Abenomics' "third arrow" aimed at structural reform and provide the detail necessary to translate these ambitions into action. The EBC offers these recommendations as a "fourth arrow" to guide the Government of Japan in its efforts to set Japan on a new course of growth, stability and prosperity.

How this report is organised

Following this introduction, there are 30 chapters, addressing the concerns of EBC sector committees. The chapters summarise key issues and developments of the past year, and are accompanied by concrete recommendations for regulatory reform. We trust the information, ideas and recommendations will prove to be a positive contribution to the thinking of the Government of Japan and all other authorities, including in the European Union, who genuinely wish to see the EU-Japan trade relationship reach its full potential.

Business

Fundamentals

Human resources
Intellectual property
Retail & wholesale
Legal services
Sustainable development
Tax

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HUMAN RESOURCES

Introduction

The EBC Human Resources Committee has for many years been concerned at Japan's bleak demographic outlook. A future shortage of skilled labour, an ageing population and a declining birth rate present significant challenges for domestic and foreign-owned businesses and for the long-term vitality of the Japanese economy. Several forecasts suggest that the population of Japan will halve by 2050. The EBC sees only four ways to combat this decline: increasing productivity, introducing more women into the labour force, increasing the birth rate and/or increasing the number of immigrants. The EBC believes that policies in all four areas are needed to retain a skilled and competitive workforce.

Prime Minister Abe's "third arrow" for economic growth includes policies that directly impact human resource capital: strengthening the global position of Japan's universities, introducing the Test of English as a Foreign Language (TOEFL) as a university entrance requirement, extending periods of parental leave, and supporting re-employment of those above the retirement age. While the EBC supports these ideas, we do not believe that they will be enough: other factors also need to be addressed. One such factor is the low level of international experience within many Japanese companies, exacerbated by their failure to capitalise on the knowledge and experience gained by students who have studied abroad. This unfortunately discourages students from pursuing opportunities to go abroad, at a time when global exposure is vital. They may be further discouraged by the fact that the traditional period for companies to recruit students is during their fourth year at university, precisely the time when those opting to study abroad would be absent, meaning they would miss out on the opportunity to be hired. The EBC understands that the Government is attempting to resolve this situation, and feels that significant changes will be required for measures to be effective.

Of high priority is the desperate need to motivate and facilitate the return of Japan's female population to the workforce. Initiatives such as the "Short-Time Regular Employee System" (*tanjikan-kinmu-no-seishain seido*) have been introduced, but are not generally well-known or utilised. As a result, many of Japan's housewives remain unwilling to enter the workforce, in the mistaken belief that to do so would require a commitment to becoming a regular employee (*seishain*). This can only be described as a waste of available resources. Prime Minister Abe has raised the issue of increasing female participation in the labour market as part of his growth strategy. However, the EBC is concerned that the proposed measures may be less effective than intended. Firstly, the current tax system acts as an incentive to work only part-time since, provided the salary remains below a certain threshold, those employed on a part-time basis are not required to pay pension and insurance premiums and can be covered instead by their spouse's payments. Secondly, it has been reported in the media that the Government is considering extending the current one-year parental leave to three years, thereby encouraging women to leave the workforce for longer, increasing the difficulty for them to return, and possibly dissuading employers from hiring anyone who could be absent from the workplace for three years. The EBC believes that instead, greater effort should be made to support women in the workplace, by offering more public child care centres and also private child-minding services. Furthermore, more needs to be done to support and encourage men to take child care leave.

On a positive note, the EBC commends the Ministry of Justice and the Japanese Government on the changes they have introduced related to re-entry permits and extension of visa periods. The new system has improved the attractiveness of Japan for foreign professionals. Continued improvements to both immigration and other policies impacting foreigners are crucial if Japan is to compete on the global market, including to the "Points System for Highly Skilled Workers", which has not been effective so far. For example, Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees. However, amendments are still required to enable the refund in full of all mandatory Japanese pension fund contributions to expatriate workers leaving Japan, abolishing the current limit of the last three years of premium payments. The Government of Japan should act quickly to conclude social security agreements with all remaining EU Member States as well as with Norway and Iceland to lessen the burden on both employers and employees and to avoid double payments. A comprehensive FTA/EPA between the EU and Japan should aim to streamline the process of brokering multiple bilateral agreements on social security pension reimbursement. It would also provide an opportunity to revise all visa and work permit requirements between the EU and Japan with a view to creating a more integrated labour market.

Key Issues and Recommendations

■ Immigration policies

Yearly status report: good progress. With the amendment to the Immigration Control Act leading to effective removal, in practice, of the re-entry permit, Japan has made considerable improvements to the visa process. There are, however, some areas that can still be improved.

Recommendations:

The Government of Japan should:

- Introduce on-line applications.
- Further revise immigration policy to encourage the entry of skilled labour to Japan. For example, in the absence of an applicable university degree, lower the unnecessarily high requirement for ten years experience “in the industry” to five years.
- Automatically grant work permits to spouse visa holders so that multinational companies can attract the best talent to postings in Japan.
- Create a new category for permanent-residence holders eligible for the benefits of “highly skilled professionals”.

■ Work place diversity

Yearly status report: no progress. Japan’s future prosperity depends greatly on maintaining an adequate workforce that can support its ageing population and drive its economy. By far the easiest way to increase the working population would be to increase female participation. The EBC strongly urges the Japanese Government to place more focus on workplace diversity and to support and encourage more female participation in the workforce and more male participation in household and child-rearing activities.

Recommendations:

- Remove the “spouse special income tax credit (*haigusha-tokubetsu-kojo*)” which discourages “dependent spouses” from earning more than 1.4 million yen annually, and consider other incentives that encourage more participation in the workforce.
- Raise awareness of the “Short-Time Regular Employee System (*tanjikan-kinmu-no-seishain seido*)” within corporate Japan, and incentivise companies to use the system through tax breaks, benefits or other means.
- Vastly increase and improve the infrastructure necessary to ensure sufficient child-care facilities, systems and staffing to support female participation in the workforce and male participation in the home, while discontinuing any consideration of extending child care leave.
- Introduce employment legislation that encourages the creation of a competitive workforce based upon performance and not on long-term employment. Adequate protection of employees is required, but employers also need a legal framework within which to remove non-performing workers.

■ Pensions

Yearly status report: gradual progress. Social security agreements have been concluded or are being negotiated with Belgium, France, the UK, Germany, The Netherlands, the Czech Republic, Ireland, Spain, Italy, Switzerland, Luxembourg, Hungary, Ireland and Sweden. Japan is also contemplating agreements with Slovakia, Finland and Austria. For the nationals of countries without an agreement, refunds of mandatory contributions to Japanese pension plans remain capped at a maximum of three years.

Recommendations:

- Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers. Additionally, benefits should be paid out without the requirement for 25 years of contributions into the system.
- Contributions made to foreign-based pension plans should be subject to the same tax relief as contributions made to pension plans in Japan.
- The Government of Japan and EU Members States should swiftly conclude mutual social security agreements.

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INTELLECTUAL PROPERTY

Introduction

Japan remains one of the world's most attractive markets for luxury products and is, therefore, among the principal targets for counterfeit goods. Most fake products entering and circulating in Japan are sold through the Internet. The problem stems from Japan's legal system, which allows the import of fake goods if they are for personal use. There is an inflow of counterfeit sales through websites based overseas targeting Japanese customers from outside Japanese jurisdiction as well as through mid-sized auction websites in Japan. Moreover, although major auction websites and shopping malls can easily remove obvious counterfeit products, removal is more difficult when the information on the screen provides no prima facie evidence that the goods are fake. It is thought that over 20% of goods sold in this way as well-known brands are, in fact, counterfeit goods.

In the last few years, the Japanese authorities have started to more pro-actively counteract violations of intellectual property rights. However, notwithstanding important legal improvements and encouraging results following intensified surveillance over the past few years, crucial issues remain unresolved, as indicated by the very high number of cases of counterfeit products handled by the Japanese Customs Authorities every year. During 2012, some 1,117,592 counterfeit products were seized. Because not all imported goods are checked by Customs, substantial amount of counterfeit goods continue to flow into Japan. Clearly, additional resources are needed to achieve a higher level of detection and deterrence.

Nevertheless, the EBC welcomes the efforts that have been made by the Japanese authorities to protect intellectual property rights, notably through new laws and revisions of existing laws. In 2007 under the Customs Acts, it became possible for rights holders to request an image of a suspended product to be sent to them by e-mail rather than having to check the product in person at the Customs Offices, as was the previous rule. Reform of the rules for applying the Act on Specified Commercial Transactions has also resulted in improvements. This measure aims to strengthen control of the identity of vendors on Internet auction sites, by compelling vendors to furnish their complete identity data when selling twenty or more luxury brand goods. Failure to comply with this obligation may lead to the Ministry of Economy, Trade and Industry (METI) demanding that the relevant vendor is banned from selling goods on the auction website. This is an effective tool, but its potential will only be realised if it used more systematically.

The major source of counterfeit goods entering Japan is China, with 94% of the goods seized by Customs imported from there. Despite action taken by major Japanese internet portals, such as Yahoo Japan!, Rakuten and DeNa, to remove counterfeit goods being sold via Japanese portals, sites based overseas targeting Japanese customers from outside Japanese jurisdiction can still be accessed directly via Internet search engines. So far, negotiations between Japan and China on counterfeit products have failed to bring any significant results. However, the EBC hopes that Japan and China will shortly introduce measures against counterfeits, given the threat such goods pose to consumer safety, employment and tax revenues.

The measures taken by Japan to remove counterfeit goods from sale on the Internet are as advanced or better than those set up by the USA and European countries. However, Japanese regulations remain inadequate in respect of trademark violations, failing to prohibit the import of counterfeit goods for "personal use" and continuing to tolerate parallel imports, which imply inadequate border control, thereby facilitating the entry of fake goods into Japanese territory. Japanese police and prosecutors have tremendous difficulty proving that a counterfeiter knows that the goods distributed are fake, which is currently a prerequisite for taking action. The difficulty in proving awareness allows some importers to continue importing counterfeits unpunished.

The EBC believes that any future negotiations on an EU-Japan FTA/EPA should include discussions on IPR, in order to further improve the situation and to establish common rules and principles.

Key Issues and Recommendations

■ Fake goods on the internet

Yearly status report: some progress. The Internet remains the principal instrument for purchasing fake goods in Japan. Auction site operators have taken action to counter this type of sale by strengthening measures against repeat counterfeiters, such as increasing surveillance and removing fake items on the basis of information from rights holders. However, enforcement of the Act on Specified Commercial Transactions is virtually non-existent as it is not really applicable to goods sold on mobile auction sites.

Countermeasures, especially those against websites managed by Chinese counterfeiters, which have now been removed from the major Japanese auction sites, have so far proven insufficient. Although the Consumer Affairs Agency requests consumers not to purchase fake goods by publishing the URLs of counterfeiters, this is hardly effective.

Recommendations:

- The Act on Specified Commercial Transactions should be strengthened and expanded to cover mobile auction sites.
- Japan should work with China to reinforce measures against counterfeiters in China by providing the Chinese Authorities with information available in Japan about counterfeiters.

■ Imports for personal use

Yearly status report: no progress. The import of counterfeit goods for “personal use” is still legal in Japan, a loop-hole used by persons wishing to import fake products in small quantities for commercial purposes without legal risk. In the past couple of years, upon discovering a suspicious product, the Customs Authorities have adopted the practice of sending a letter to the recipient of the package requiring confirmation of authenticity and purpose. At least 90% of recipients used to decide to abandon the counterfeit goods ordered upon receiving such a letter, but the efficiency of the system is gradually being eroded as an increasing number of importers are becoming aware that the goods can be imported under the guise of “for personal use” and that these letters are non-binding.

Recommendations:

- Japan’s Trademark Law should be revised to prohibit the importation of counterfeit goods regardless of whether they are meant for personal or commercial use, as this is the only way to ensure that no such products are imported.
- In the meantime, improvements should be made by requiring the importer, whoever he/she is, to prove conclusively that the goods imported are for personal use.

■ Designs

Yearly status report: no progress. Procedures for applying for protection of intellectual property rights in respect of designs remain too complex and expensive, effectively denying foreign companies the benefit of the protection enjoyed in Europe and most other markets.

Recommendations:

- Application fees should be reduced and examination procedures eliminated or substantially alleviated.
- A more stringent approach should be taken by Japanese courts when interpreting the similarity of designs.

Vacant

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RETAIL & WHOLESALE

Introduction

The Japanese retail market is one of the largest and most vibrant in the world. After many years during which the presence of European retailers was more or less limited to the luxury sector, the last ten years have seen the rapid establishment of new European retailers in Japan, both in fast fashion and home interiors. Their success clearly benefits Japanese consumers by offering greater choice, often better prices and, frequently, completely new products previously not available on the market. The success of European retailers in Japan also benefits the Japanese economy at large – it creates considerable employment and helps to revitalise many cities that were previously in decline. Japanese retailers and wholesalers gain from the presence of European competition as it provides incentives to further strengthen their global competitive edge. Very concrete examples of this are Uniqlo and Nitori, which are today stronger than ever.

Despite recent successes, European wholesalers and retailers still face considerable barriers in the Japanese market. Firstly, while there has been a marked expansion of foreign retail activity in the speciality retail channel (albeit with many outlets operating via franchises or under licence to Japanese companies), it has proved difficult for foreign retailers to take advantage of global-scale logistics when entering the Japanese market. Secondly, the process of developing and opening new retail outlets remains fraught with restrictions, inefficiencies and delays. Thirdly, although the EBC Retail & Wholesale Committee understands and shares the Government of Japan's concerns regarding consumer protection, it believes that European rules more than adequately address these same concerns, ensuring safe and good-quality products. Hence, the Government's insistence on applying Japan's rules and regulations to products that have already met European standards serves only to create barriers to trade. Examples of such barriers are Japan's unique labelling rules, inflexible food sanitation rules that are not related to the safety standards themselves, and non-recognition of global standards or European approvals. These barriers are particularly damaging to companies with a global supply chain. Moreover, procedures for importing, certifying and labelling various consumer products continue to be overly costly and complex, due again to Japan insisting on additional product testing against specifically Japanese standards, even where products are already covered by international and European standards. This problem affects several areas, as described in the recommendations that follow.

Japan is vigorous in enforcing copyright, trademark, and other intellectual property laws and regulations. Japan Customs screens and stops many counterfeit items at the border but, as the Intellectual Property section of this report indicates, much more could be done in this regard. In particular, Japan has adopted some of the world's most lenient rules and regulations pertaining to the import and distribution of 'grey market' goods (i.e. genuine goods authorised for sale and distribution outside Japan but whose distribution within Japan has not been authorised by an intellectual property owner or other responsible party). Such leniency undermines authorised Japanese distributors, wholesalers and retailers, and is potentially damaging to brand management and marketing. Importantly, many importers of grey market items manage to side-step safety testing requirements, thus at times endangering the Japanese consumer.

The EBC earnestly hopes that, in the process of the negotiations towards an EU-Japan FTA/EPA, many of the barriers met by European retailers and wholesalers will either disappear or be eased. The EBC believes that these negotiations offer an excellent opportunity to demonstrate the EU's own high safety standards and that there is no practical purpose or benefit in further testing products that have met these standards before they can enter the market. Although there is still much progress to be made, the EBC is already seeing some encouraging signs of better understanding by the Japanese authorities of the problems faced in Japan by European retail companies operating with a global supply chain. At the same time, many domestic companies are increasing their presence in overseas markets and so experiencing first-hand the burden of Japan-unique regulations.

The EBC can see no reason why products already certified for the European market have to undergo testing and certification anew if they are to be sold on the Japanese market, and vice-versa. As standards for most retail products are similar, the EBC's Retail & Wholesale Committee believes that the EU and Japan should swiftly move through the FTA/EPA to establish mutual acceptance of standards and certification, which will benefit companies in both markets.

Key Issues and Recommendations

■ Prohibitive import, testing and certification

Yearly status report: no progress. Japan's reluctance to accept EN (European standards) and ISO standards or CE (conformité européenne) markings delays the introduction of new products to the Japanese market and increases import costs. The EBC, while understanding the need to ensure the safety of the consumer, specifically requests the Japanese Government to revise its legislation applying to products with food contact and the related import system to facilitate smoother trade.

Recommendations:

- Japan and the EU should mutually accept each other's regulations governing the application process for importing and selling/using products to lessen the need for re-testing.
- Japan should enable "food contact" products to be tested in any laboratory approved by the Government of Japan regardless of the country of export. Pre-registration testing should also be allowed outside of Japan.

■ Labelling of household products

Yearly status report: some progress. The Household Goods Quality Labelling Act regulates how household goods within the scope of the Act are labelled. The legislation requires 90 specified product categories, grouped into four areas (textile goods, plastic manufactured goods, electric appliances and miscellaneous manufactured goods), to be labelled with information as defined by the Act. The EBC welcomes the Consumer Affairs Agency's (CAA) recent activities considering possible amendment of the law. The CAA plans a two-step process: short-term revision of the Act, and a longer-term revision of the framework of the act itself. However, the EBC believes this process lacks a sufficiently comprehensive approach.

Recommendation:

- The long-term revision should focus on aligning the information required to the actual product. The CAA should focus and take the needs of global companies supplying markets all over the world into better consideration. This will, without hurting the Japanese consumer, also be beneficial to Japanese companies operating in foreign markets.

■ Shoe quota

Yearly status report: new issue. Various shoe tariff lines are covered by quotas. By means of these quotas, imported shoes can benefit from a lower tariff. The allocation is partially based upon historical import figures while part of the total volume is dedicated to "newcomers". The major problem with the current system is the lack of transparency and that companies not truly involved in the shoe business retain quotas, which they "sell" to other companies. This behaviour is illegal, but still persists.

Recommendation:

- The Ministry of Economy, Trade and Industry (METI) should improve monitoring of the situation to reject applications from entities that are not properly trading shoes and release their quotas. It is also recommended that METI should implement stricter penalties for companies taking unfair advantage of the system.

■ Superior bargaining power

Yearly status report: new issue. The Antimonopoly Act (AMA) contains legislation relating to the abuse of a superior bargaining position, in order to protect weaker companies (often SMEs) and penalise larger companies that force them to agree to undesirable action. This is an issue for both domestic and foreign companies. Unfortunately the current legislation is vague, making compliance difficult, and the Japan Fair Trade Commission (JFTC), in its eagerness to protect weaker companies, is contradicting normal business practices that are common in Europe and the United States, especially on the issue of agreed shared loss-taking.

Recommendation:

- The AMA should be amended to take normal global business practices into better consideration. While the EBC fully understands the background to the legislation - to protect a weaker company from being forced into taking undesirable action - we request that the AMA be changed to allow shared loss, where both parties agree to this.

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LEGAL SERVICES

Introduction

2013 has been a year in which there has been no perceptible improvement in the position relating to foreign lawyers in Japan. Accordingly our key issues and recommendations remain unchanged from last year.

The one item of draft legislation in the pipeline was the proposal to permit foreign lawyers to operate through *bengoshi hojin* (corporations), and therefore be able to open branches. This draft legislation, which followed the report of the Foreign Lawyers System Study Group in 2009, had originally permitted the establishment of *bengoshi hojin* consisting of both foreign and Japanese lawyers. However, following some unfounded opposition in the Diet, the draft was changed so that the *bengoshi hojin* established by foreign lawyers must consist entirely of foreign lawyers – significantly limiting the usefulness of the proposal. There is only a relatively small number of international firms consisting solely of foreign lawyers. Even this piece of legislative reform has not been progressed due, in part at least, to a lack of legislative time. We also understand that progress will not be possible on any other legislative initiative relating to foreign legal firms until this one has been dealt with.

While the time taken for registrations of foreign lawyers, *gaiben*, does not seem to have become materially longer, and we are sure that the Ministry of Justice (MoJ) tries to be helpful, it has not become noticeably shorter either, and the fact remains that, due to the many organisations involved in the approval process, the procedure is protracted and cumbersome. It takes too much time in an age when international law firms, at least, need to move people around quickly to meet customers' requirements. The lengthy time frame in Japan, in comparison to the much shorter time taken to register as a foreign lawyer in places such as Singapore, must lead to questions about whether Tokyo really wants to become an international financial centre. It is, furthermore, difficult to send junior staff to Japan as a *gaiben* as they need at least three years' experience to be able to register. An additional requirement is that out of the three years, two years need to be obtained outside of Japan, a requirement the EBC thinks is at odds with Japan's wish to become more international and global.

The EBC Legal Services Committee requests that the FTA/EPA negotiations tackle both the issue of mutually recognising the status of lawyers so as to alleviate the cumbersome registration process in Japan, and the need to improve market access for firms with both *gaiben* and *bengoshi* with regard to setting up branches.

Key Issues and Recommendations

■ Recognition and approval as a foreign lawyer in Japan

Yearly status report: questionable progress. In order to become registered as a foreign lawyer (*gaiben*) in Japan, three years of professional experience in the foreign lawyer's home law is required, of which two years have to be obtained outside Japan. This rule is in stark contrast to the rules governing Japanese lawyers (*bengoshi*), who are not required to have any post qualification experience before being recognised. The EBC believes that this practice is not only discriminatory, but also makes little sense as the lawyers are already acknowledged by their jurisdiction of qualification. If there is to be such a rule, what is important is the experience in home jurisdiction law, not where it is practiced. The procedure for admitting foreign lawyers as *gaiben* also still imposes undue costs on foreign firms and individuals. A streamlined application form has, in general, shortened the process, but the requirement for approvals from both the MoJ and committees at the *Nichibenren* and local bar associations inevitably gives rise to delays.

After 25 years of operation, the *gaiben* system is in need of a thorough overhaul. Changes in the system could solve a number of the current frustrations.

Recommendations:

- The rule requiring a specific number of post-qualification years of experience should be abolished. As an immediate first step, while a more thorough overhaul is completed, the legislation should be amended such that all experience in home jurisdiction law is recognised, regardless of where it has been practised.
- Continuing focus needs to be put on accelerating the application procedure for *gaiben* registration to the greatest extent possible.
- An overhaul of the existing system should be undertaken. This would enable changes such as the registration of firms rather than individuals, which would do much to eliminate frustrations with the existing system.

■ Branches

Yearly status report: no progress. Under the current rules, it is not possible for a *gaiben* law firm, or a joint enterprise between *gaiben* and *bengoshi*, to open more than one office in Japan. Such a possibility is open to *bengoshi*, who may do so through a *bengoshi* corporation or *hojin*. Currently such a structure is not available to *gaiben*.

In December 2009 the final report of the Foreign Lawyers System Study Group was published. This committee recommended that *gaiben* should be able to establish corporations with other *gaiben*, and also with *bengoshi*. Draft legislation was introduced to implement the report's recommendation, however it has been opposed in the Diet and revised so that *gaiben* will now not be able to establish a corporation with *bengoshi*. This revision will significantly limit the usefulness of the legislation.

Recommendation:

- The proposed legislation should be amended to reinstate its original wording and enacted as soon as possible. An even better (and simpler) solution would be to abolish the restriction on branching, which is archaic and does not suit the needs of either domestic or international law firms.

■ Limited liability

Yearly status report: no progress. The EBC continues to recommend the introduction of a limited liability structure for lawyers in Japan, for the benefit not only of foreign but also Japanese lawyers. It has been considered fair to permit professionals in many other parts of the world to operate within such a structure. For foreign lawyers, this could be achieved by permitting them to operate through a branch of their home entity rather than as separate individuals, which only an overhaul of the existing system could achieve.

Recommendation:

- A limited liability structure should be made available in Japan for both foreign and domestic law firms, and foreign firms should be able to practice in Japan through branches of their international firms. This could be achieved by an overhaul of the existing *gaiben* system to permit foreign lawyers to operate in Japan through branches of their home entity.

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SUSTAINABLE DEVELOPMENT

Introduction

In an increasingly globalised world of dwindling natural resources and escalating social tensions, the appeal launched in the 1987 report of the Brundtland Commission (the World Commission on Environment and Development) to balance the needs of the present with those of future generations appears an ever more daunting challenge. Harnessing the innovative potential of business across all industries to address the issues of sustainable development and climate change is imperative for the survival of the broader system that enables life and business as we know it.

The EBC Sustainable Development Committee reflects the commitment of European companies to contribute to sustainable development in Japan and aims to facilitate their access to the Japanese market. This includes efforts to identify any trade or investment barriers that block such access and advocate their removal. European business is keen to enter into a dialogue with Japanese society, government and business to facilitate reform. Some of Europe's companies trading in Japan are world leaders in sustainability, but find themselves at times held back here by a conservative and introspective business environment that is slow to embrace the opportunities of a more sustainable business model. On the other hand, Japanese society as a whole appears open to change of this sort. The EBC believes companies that fail to seize the moment and align with the direction in which the world community is now moving will fall behind. The same might also be said for an entire economy. If sustainable development has taught us anything, it is that it is always a mistake to adhere to an outdated business model simply because the alternative appears to present higher short-term costs. The implementation of sustainability concepts does not imply reduced competition or profitability: in fact, the reverse is true. Consequently, the aim should be to provide a platform for all businesses in Japan to improve their commitment to sustainability. We believe this will deliver benefits to the economy as well as the environment, and crucially, enable Japan to achieve its goal for lower greenhouse gas emissions.

In Japan as in other advanced countries, buildings are the foremost producers of greenhouse gases. Studies have shown that up to 40% of greenhouse-gas emissions come from buildings, a much higher proportion than from the transport and industrial sectors. In light of this statistic, improving building performance will play a crucial role in creating a sustainable future and government legislation will be vital to ensuring that the necessary energy-saving technologies and materials are adopted and implemented. Japan is lagging behind in this respect. For example, single glazing is still a common feature in Japanese buildings, whereas Europe moved to double and even triple glazing long ago. In Japan, to date, the focus has been on "appliances". For example, Japanese manufacturers are leaders in producing low energy-consuming air-conditioning equipment. What is missing is the focus on the actual building. Buildings should be constructed in such a way that they do not require the addition of elaborate energy-consuming equipment in the first place. In terms of energy use, the exterior envelope is the most important system. It should be well-insulated and use components that transfer as little thermal energy as possible - heat from outside to inside in summer, and from inside to outside in winter. European manufacturers offer some of the best solutions on the market, but increased efforts are needed to reduce regulatory hurdles to their adoption and to promote their acceptance by the Japanese construction industry.

The EBC encourages the Government of Japan to take a much stronger stand on, and implement measures to improve, sustainable development in all key areas, including infrastructure, business, and consumer behaviour. The EU strategy, for example, has the following targets: put an end to the destructive link between economic growth and damage to the environment; encourage businesses and the general public to use objects that have been produced responsibly; aim to have public authorities buy products and services that do not damage the environment; expand the market in technologies and innovations that are environmentally-friendly; and improve the welfare of animals both within the EU and beyond.

The EBC Sustainable Development Committee believes that, if Japan is to reach its environmental goals, it will need to demonstrate a dramatic acceleration of progress in all the areas indicated above. The EU-Japan FTA/EPA offers the opportunity to create a key vehicle for further cooperation and coordination in sustainable development.

Key Issues and Recommendations

■ Improved sustainable development awareness and behaviour

Yearly status report: new issue. Japan, while at the forefront of developing environmentally friendly technology, is lagging behind when it comes to exhibiting environmentally friendly behaviour. There are very few incentives to encourage consumers and businesses to change. The Government should implement measures that better guide behaviour towards sustainability, which the EBC believes in turn will help Japan reach its environmental targets.

Recommendations:

- The Government of Japan should raise public awareness regarding the benefits of sustainable development.
- Better collaboration between Japan and the EU in setting environmental targets and agreeing on the actions required to achieve these, should be a key part of the EU-Japan FTA/EPA.

■ Organic food

Yearly status report: no progress. Organic food represents only about 0.4% of all food sold in Japan. This is about 10 times lower than in Europe and possibly the lowest level amongst developed countries. Japanese agriculture is still over-reliant on chemical inputs in the form of pesticides, fertilisers and hormones. This situation is clearly undesirable from both an environmental and consumer perspective. Japan should take the necessary measures to rapidly increase the growth of the organic food sector, including the development of local organic and sustainable agriculture.

Furthermore, although the EBC is pleased that supplementary certificates from EU embassies are no longer needed, the requirement that an individual organic certificate needs to accompany every shipment remains an administrative burden for both importers and exporters.

Recommendations:

- Abolish the need for individual organic certificates for every shipment. An annual certificate should suffice.
- Expand organic JAS to include animal-based products.
- Abolish tariffs on organic food (since organic food already carries a price premium, tariffs only serve to make such food exorbitantly expensive, further discouraging its purchase by consumers and slowing the growth of the organic food sector).
- Encourage more sustainable farming through the use of fewer pesticides and antibiotics.

■ Framework for sustainable construction

Yearly status report: some progress. Buildings, in Japan as in other advanced countries, are the foremost producers of greenhouse gases. Studies have shown that up to 40% of greenhouse gas emissions come from buildings, a much higher proportion than from the transport and industrial sectors. The average lifespan of a building in Japan is 30 years, suggesting a lower level of building sustainability in Japan compared to the United Kingdom, where it is 90 years. Moreover, insufficient insulation, which is common in Japan, leads to a large transfer of thermal energy. To catch up, Japan needs to implement technology from abroad, which means promoting its use and facilitating importation of the necessary foreign materials.

Recommendations:

- The Government of Japan should introduce an incentive system to make sustainable and green buildings more attractive to construction companies and consumers.
- The Government of Japan should take advantage of European technology in the construction sector to reach its goals for greenhouse gas emissions.

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TAX

Introduction

The EBC welcomes the stimulation given to the Japanese economy by reducing the corporate tax rate to 38% as of April 2012 and 35% as of 2015, thus bringing the rate closer to international levels. This will improve the competitiveness of Japan for the benefit of both Japanese and foreign companies. The magnitude of the challenges still ahead for the Government, however, cannot be exaggerated. The uncertain outlook of the world economy, in combination with the Japanese public's lack of confidence in their social welfare system, is suppressing consumption below already low levels. Increasing the consumption tax in steps to 8% and then 10% in April 2014 and April 2015, respectively, should help to restore the finances of and confidence in the social welfare system at least.

Aware of the severe fiscal constraints the Japanese Government is facing, the EBC's recommendations address the fact that insufficient transparency and predictability in tax rules create uncertainty and lead to lower investment and economic activity. We believe that addressing transparency issues thoroughly and as a matter of urgency would be the most efficient way to promote business without having to spend extra money or undermine the tax base - hence tax revenue would remain the same. Unfortunately, attempts made so far by the Government of Japan to improve the transparency and predictability of the tax regime have been inadequate and, as a result, the situation has not substantially changed. Improvements made to the formal tax ruling system, *Bunsho Kaito*, did not lead to a significantly higher number of tax rulings. While the EBC is pleased to see that some progress has been made regarding secret comparables in transfer pricing, we are disappointed to note that confidential taxpayer information is still leaked and that the press is still reporting on ongoing tax audits, making references to sources within the tax authorities. The EBC recommends that the Government reviews recent changes in the way in which the relationship between taxpayer and tax inspector is organised in European jurisdictions like The Netherlands and the UK and how these changes have improved transparency, reliability and predictability for the taxpayer and the tax administration alike.

The EBC is happy to see that Japan is proposing to introduce the Authorised OECD Approach (AOA) into the Japanese corporate law. This is indeed a good step in the right direction. However, we are fully aware of the fact that this is still only a proposal, so while applauding this initiative we would like to point out that there are still some areas of uncertainty and inconsistency with the AOA. We believe that Japan should do its utmost to avoid deviating from OECD guidance and global practice.

When considering how to boost bilateral trade and investment, the EU and Japan should strive to mutually eliminate double taxation and withholding tax on dividends, royalties and interest, as provided for in tax treaties concluded between Japan and the UK, France, The Netherlands, Switzerland and the US. The EU-Japan FTA/EPA should, furthermore, enable employers' and employees' contributions to social security systems within the EU and Japan to be tax deductible on a mutual basis. The FTA/EPA should also provide for a mandatory arbitration clause to ensure that double taxation will effectively be solved between Japan and the individual EU Member States if the tax treaty text itself does not avoid double taxation in effect.

Tax reforms undertaken so far have been largely piecemeal and it is clear that a new approach is needed. The EBC encourages the Government of Japan to tackle its tax policy challenges upfront and address the issues detailed on the following pages as a matter of priority.

Key Issues and Recommendations

■ Research and Development Tax Incentives

Yearly status report: progress. The EBC is pleased to note that recent and planned tax reforms continue to include R&D tax incentives. Nevertheless, overseas investors are discriminated against by the Japanese R&D tax incentive regime. While Japanese rules give tax consideration to R&D expenses incurred by Japanese multinational enterprises even when undertaken overseas, no credit is given to foreign investors conducting R&D in Japan, unless the related expenses are borne locally. This discrepancy is due mainly to the focus of the tax rules on Japanese domestic enterprises that naturally take the cost of R&D at the level of their Japanese headquarters, a practice that is not very common among foreign subsidiaries in Japan.

Recommendation:

- Research and Development conducted in Japan by a foreign investor should be eligible for tax benefits here, even when the associated expenses are not borne by the investor's Japanese subsidiary.

■ Accountability and confidentiality

Yearly status report: progress. Taxpayers may now seek written clarification of specific transactions as a result of changes made to the *Bunsho Kaito* system under the 2008 tax reforms. Despite this improvement, an overall lack of transparency and systematic accountability in the domestic tax regime continues to impede the development of business in Japan. European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. The number of tax audits on which information has leaked is unprecedented in comparison to any EU Member State. The press often makes reference in news articles on such audits to sources within the tax authorities. The EBC views any "leaking" of information protected by Japanese taxpayer confidentiality laws with extreme concern. An open relationship, based on mutual trust and providing transparency and certainty is vital for investors to be willing to invest and for governments to collect the applicable revenues and maintain the tax base in the most efficient way possible. To this end, the Dutch and British governments have introduced systems in their tax collection processes comprising Horizontal Monitoring, Risk Rating and Senior Accounting Officers, which in essence shift the tax compliance and monitoring burden from the tax authorities to the taxpayer. In return, the tax authorities undertake to provide timely advice and clearance regarding their position on disclosures, and to respond faster to any questions and take clear positions. Moreover, tax audits are carried out on a less frequent basis and are less detailed. The use of Horizontal Monitoring, Risk Rating, and Senior Accounting Officers offers a far more efficient way for taxpayers and tax authorities to work together. The overall approach provides certainty to the taxpayer, while maintaining the same amount of tax revenue for the government.

Recommendations:

- The tax authorities in Japan should be obliged to accept and process applications for tax rulings, and tax law should provide for the right to request and obtain tax rulings.
- The Government should ensure that the press is not given access to confidential tax audit data. The tax administration should be held accountable for secrecy duty violations, if any leakage comes from their side.
- The Government should consider the merits of introducing a system offering Horizontal Monitoring, Risk Rating, and Senior Accounting Officers.

■ Authorised OECD Approach

Yearly status report: new issue. Japan is entertaining the idea of introducing the AOA into the Japanese corporate law. While this is a step in the right direction, the EBC would like to point out that there are still some uncertainties or inconsistencies in the Japanese plan compared with the OECD approach.

Recommendations:

- Japan should introduce the AOA, properly aligned with OECD guidance and global practice.
- Consideration should be given to accepting risk transfers between a permanent establishment and its head office, where that risk transfer meets the appropriate criteria of a true transfer of risk (e.g. reinsurance).
- Clarification of the distinction between head office cost allocations and the provision of services by head office should be provided.

■ Transfer pricing

Yearly status report: limited progress. The Japanese tax authorities have clarified some of the requirements of transfer pricing documentation and the consequences for failure to comply with these requirements. As a result, it appears that the right to base a transfer pricing assessment on secret comparables has in theory been somewhat restricted. However, at the same time there has been an alarming increase in the use of domestic corporate tax rules relating to donations to make assessments in relation to transfer pricing. This has been done ostensibly to avoid the mutual agreement procedures arising under Japan's tax treaty network. In addition, there continues to be inconsistency between the basis for assessment of transfer pricing during an audit and the basis for assessment under the APA (Advanced Pricing Agreement) system.

Recommendations:

- The EBC recommends that all cross border transactions should be dealt with under transfer pricing legislation and not under domestic corporate tax rules relating to donations.
- There should be consistency between the transfer pricing methodology for audit assessments and that used for APAs.

■ Corporate Restructuring

Yearly status report: progress. The current tax treatment of cross border and triangular mergers is, in practical terms, a barrier to those market entrants who have no established business in Japan but aim to use their own shares to acquire a Japanese company. Current rules do not permit tax deferral in respect of stock swaps between foreign and domestic companies, even if the transaction is carried out using a Japanese special purpose company. Eliminating discriminatory treatment of foreign shares used as consideration in mergers with Japanese companies is the most important policy step needed to facilitate foreign direct investments into Japan.

Criteria that are complex and in practice difficult to meet in tax qualified restructurings are adverse to the natural goals of foreign-affiliated and domestic companies to reduce the number of peripheral legal entities and infrastructure costs. Removing potential obstacles in administration, including tax, should therefore be the aim of tax policy makers.

Recommendations:

- Current rules should be revised so as to permit a deferral of capital gains tax for shareholders receiving shares from a foreign company with no previous operations in Japan.
- Rules and regulations underpinning the corporate reorganisation laws should be further simplified and clarified to reduce both the cost and the discretion that the tax authorities retain in defining key concepts.

■ Tax treaties

Yearly status report: progress. Japan concluded new tax treaties last year with Switzerland and The Netherlands and is currently re-negotiating its tax treaty with Germany. The EBC welcomes treaties that include the exemption of withholding tax on royalties and qualified dividends and interest.

The treaty between Japan and The Netherlands contains a mandatory arbitration clause to ensure that double taxation will effectively be solved between Japan and The Netherlands if the treaty text itself does not avoid double taxation in effect. In practice this is an important improvement and the EBC would welcome its inclusion in all future treaties.

Recommendations:

- The EBC encourages the Government of Japan to review current tax treaties with EU Member States.
- The EBC requests that any new or revised treaty addresses the problems with withholding tax on royalties and qualified dividends and interest.

Financial Services

**Asset management
Banking
Insurance**

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ASSET MANAGEMENT

Introduction

The professional investment management industry in Japan continues to provide important benefits to society by helping to prepare investors for their financial future. Due to the ageing of the population and to stubbornly low birth rates, the burden on social security and pension systems continues to swell. Moreover, the prolonged low interest rate environment precipitated by the global financial crisis of 2008, coupled with the continued strength of the Japanese yen vis-à-vis other major currencies, has driven public and private investment pools to seek higher returns from financial products both from within and from outside Japan. The demand for increasingly sophisticated investment expertise has continued in 2013. The importance of basic operational controls and proper oversight of fiduciary responsibilities has been reemphasised by unfortunate cases of malfeasance.

To meet the critical needs of users of investment management services, it is imperative that the Government of Japan and in particular the Financial Services Agency (FSA) continue with reform measures designed to provide the investing public with appropriate products, both new and innovative, in a flexible, user-friendly investment management framework that promotes growth and avoids hampering expansion. The EBC is therefore looking forward to the new initiative on Individual Savings Accounts. We believe that it is important for the Government of Japan to introduce a system with a sufficiently long period of tax exemption, to ensure that a broad range of investment options are allowed, and to incentivise banks and other market participants to support and give robustness to the new scheme.

The EBC continues to believe that further development of a “free, fair and global” market is the only way forward for Japan to become an international financial centre. The regulatory environment in Japan continues to impose unnecessary and costly burdens on investment management service providers, which ultimately hurts Japanese consumers. It was, therefore, disappointing that despite the benefits of a planned merger between the existing two industry associations, the Investment Trust Association, Japan (JITA) and the Japan Securities Investment Advisers Association (JSIAA), the merger was thwarted by a late-stage impasse brought on by the industry associations themselves. Such regulatory burdens stifle innovation and yield inefficiencies in resource allocation.

The advances made by the EU in investment management, as well as in other areas of financial services, are recognised as leading-edge and, by working together, Japan and the EU can extend the benefits of these advances to the Japanese investing public. The EBC strongly recommends that the EU and Japan include such issues in the bilateral FTA/EPA.

Key Issues and Recommendations

■ Reports of large shareholdings

Yearly status report: progress. A revision to the Securities Exchange Law in 2006 altered the reporting system for professional investors, requiring them to report within five working days if their own stake in a listed company exceeds 5% of total stock, and every second week with regard to the consolidated holdings of the whole financial group. The EBC appreciates that the system for reporting large shareholdings (Financial Instruments and Exchange Act Chapter II-3) is helpful in promoting fairness and transparency in boardroom battles between shareholders and managers. However, if an investment management company that is subject to regulatory supervision files a statement affirming no intention to actively contest, it should be subject to a less stringent reporting regime.

Recommendation:

- The requirement for investors to disclose holdings of shares in listed companies in excess of 5% every second week on a consolidated basis should not be applied to asset management companies that are not actively contesting for management control of the companies in which they invest.

■ Promotion of Japan as an international financial centre

Yearly status report: progress. The EBC applauds steps already taken by Japan to reach its stated goal of securing its place as an international financial centre, which include measures to accommodate employees transferred to Japan from foreign countries, to reconcile certain differences in taxation schemes applicable to investment products, and to unify financial services regulation through the introduction of the Financial Instruments and Exchange Act (FIEA). However, many impediments remain, and the pace of change has been too slow to attract positive attention from the international community. The FSA's effort to push reform measures within its control is highly commendable, but without a holistic approach that encompasses all key functions, including tax and industry associations, continuing to push forward on certain fronts while retreating on others will fail to garner the respect and trust of the international community.

Recommendation:

- To further promote Japan as an international financial centre, the Government should develop a more holistic plan for reform that encompasses all relevant and key functions, including tax and industry associations, in order to strengthen the competitiveness of the local financial sector and to earn the respect and trust of the international community. This should include reform of transfer pricing, stabilising of tax rates on listed equity securities and merging of industry associations.

■ Nippon Individual Savings Accounts (NISA)

Yearly status report: progress. The EBC believes that the Government's recent approval of the NISA Law, which establishes a framework for a new form of individual savings and investment account from 2014, is an important step toward encouraging savings and investment. The law's stated goal is to reverse lower savings rates among individuals and to provide an additional channel for long-term asset growth, through long-term and diversified investment in listed stocks and publicly-offered stock investment trusts. However, the new law as approved allows for investment contributions of only 1 million yen per year for five years, each such contribution being tax exempt for five years. As with the Japan 401k scheme, such limited contribution allowances provide limited benefit to individuals and even less incentive to the industry participants expected to administer the scheme. The EBC supports the FSA's proposal and encourages the Government to avoid the mistakes of the 401k system by making adjustments to ensure that the NISA is effective.

Recommendation:

- To ensure that the NISA scheme meets the stated goal of helping individuals grow their assets through long-term and diversified investment, the Government should amend the NISA law prior to implementation to (a) allow sufficient contribution amounts to provide material benefit to individuals, (b) make the investment period permanent, or at least of sufficient length to provide material benefit, for example, until age 65, and (c) provide for the new scheme's robustness and smooth implementation by ensuring that market participants who will administer it can benefit from scale and business opportunities.

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BANKING

Introduction

Japan's relative prosperity has decreased considerably in recent years and, although Japanese consumers have continued to save throughout this period, their return on capital has been the lowest in the industrial world. At the same time, it is obvious that Japan has weathered the latest financial crisis much better than many other countries. Japanese capital markets were strong enough to raise substantial funds during 2009 and 2010. Therefore, Japan still remains one of the largest financial markets in the world with high savings rates.

Reform of the Japanese financial sector has been high on the Government agenda ever since the bursting of the bubble in the early 1990s. The Hashimoto “Big Bang” reforms initiated in 1998, which enabled the formation of financial holding companies, were followed by consolidation of the banking sector and efforts to clean up bad debts and non-performing loans under the leadership of Prime Minister Koizumi. Multiple financial services regulators were streamlined and a no-action letter process was introduced to enhance transparency, while limited structural reform was achieved by enabling Japanese city banks to engage concurrently in trust and banking businesses. The Japanese Government and, in particular, the Financial Services Agency (FSA) have pushed through some easing of firewalls allowing, in some cases, double-hatting of back-room functions.

After some years of stagnation in the attractiveness of Japan as a financial centre, Tokyo has started to bounce back, and the Economist now ranks Tokyo 5th up from 7th place in 2012, in the Global Financial Centre Index (GFCI), which ranks the competitiveness of global financial centres. No doubt much of this is due to “Abenomics” where the biggest impact has been seen in the stock market, as the Nikkei 225 index has grown from 8,500 to about 15,500 at the time of writing. It is, however, now crucial that structural reform is introduced to convert this short-term gain to sustainable growth. So far Prime Minister Abe’s reform plan for the financial sector has not impressed. EBC believes a more radical approach is needed to create a financial environment enabling Tokyo to represent Asia as a truly regional financial centre.

The EBC advocates a regulatory framework that recognises and reflects the differences in business models between retail banking and commercial banking. While there is an understandable need for strong consumer protection measures in the retail sector, in view of the imbalance in information and knowledge that exists between retail banks and their individual clients, the same cannot be said of banks in the commercial sector and their clients, who are generally other financial institutions or corporations. The EBC is not arguing against having a regulatory framework for the commercial banking sector, but believes regulation should avoid placing an unwarranted burden upon commercial banks. This issue is particularly relevant to the expansion of the deposit insurance system, which was established to protect the accounts of depositors in the event that a bank defaults.

Following the March 2011 earthquake and its aftermath, Business Continuity Management (BCM) has been placed high on the agenda of the banking community. Among the key issues is the need to secure and access information in the event of Japan’s communication infrastructure becoming inaccessible. One natural solution would be to duplicate or relocate the information in an offshore location. Unfortunately, current law either, in some cases, expressly forbids such action or fails to provide guidance on how it should be carried out.

Finally, working under the auspices of the FTA/EPA and with a view to making universal banking the norm in both regions, the EBC believes the EU and Japan should embrace the principle that where a bank is based in one territory with a single branch in the other territory, that branch can be granted licences covering Banking, Securities, Trust Banking, Asset Management, and Insurance, without having to establish separate structures.

Key Issues and Recommendations

■ Deposit insurance system

Yearly status report: new issue. Foreign banks have in the past been excluded from the deposit insurance system because most are branches and not subsidiaries. During 2012, several statements by the Japanese authorities have indicated an intention to include foreign branches. Such an approach would not take into sufficient consideration the differences in business models between most Japanese banks and European banks in Japan, the latter being almost exclusively focused on commercial and corporate banking where client knowledge is very different from that of the customers of the retail sector.

Recommendation:

- The Japanese Government should take into consideration differences in business models and customer profiles, before expanding the deposit insurance system.

■ Transparency and regulatory efficiency

Yearly status report: progress. Duplicated inspections by the FSA, Securities Exchange and Surveillance Commission (SESC), Tokyo Stock Exchange (TSE), Japan Securities Dealers Association (JSDA), Ministry of Finance (MOF), and Bank of Japan (BOJ) have long imposed an excessive administrative burden on regulated firms. The EBC encourages the Government to increase efficiency and transparency and welcomed the FSA's decision to release its annual inspection programme, which clarifies the focus issues for the year, and for providing pre-notification of inspections in certain cases. The FSA should in particular be complimented on improved communication, which has created a more stable environment. Despite these improvements, the overly rule-bound regulatory environment in Japan leaves little room for innovation by the regulated entity, unless there is extensive prior consultation with the regulator on precisely how the rules are to be interpreted and applied. Such a prescriptive, yet unclear, regulatory framework cannot keep up with the pace at which financial products and markets are changing.

Recommendations:

- The extensive requirements for reporting to regulators and self-regulatory organisations should be re-evaluated, and reduced to a level consistent with sound, but not excessive, supervision.
- FSA rules and regulations should be applied consistently and clarified in accordance with fair and current universal guidelines.
- The FSA and other regulators should encourage innovation and competitiveness in financial services markets by operating on the basis of published general principles for good governance.

■ Banking agency system

Yearly status report: no progress. The banking agency system introduced in 2009 requires Japanese branches of European banks to apply for a special business licence each time they plan to introduce to their Japanese customers any new banking services provided by other banking entities, even if these are branches of the same financial group located outside Japan. This noticeably impacts cross-border services in which the Japanese arm of a global financial group supports its Japanese private or corporate clients in opening accounts abroad and introduces its Japanese clients to global cash management services or other services provided out of non-Japanese branches. While the EBC supports the Japanese authorities' effort to provide an appropriate regulatory framework for cross-border transactions, the current system must be improved in order to clarify the criteria for applying for new banking agency licences and speed up the review and approval process at the administrative level.

Recommendations:

- The FSA should further clarify and streamline the application process for banking agency licences.
- The FSA should introduce a system whereby European branches do not have to apply for a special business licence each time they introduce a new product.

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INSURANCE

Introduction

The Japanese insurance market is the second largest in the world. While the market share of foreign affiliates in Japan is increasing, they continue to encounter regulatory obstacles that can limit efficient development of their businesses. Examples include reserving and solvency regulations that are inconsistent with, for example, European solvency requirements, and the lengthy, non-transparent product approval process. Future market growth in Japan will come from the ageing of the population, which will drive a need for products dealing with extended retirement, changes to family structure and rising demand for medical products. Through a principles-based regulatory regime, where the regulator strikes a careful balance between innovation and regulation, focusing on risk management and allowing flexibility, the insurance market can adapt appropriately to deal with changes in policyholder needs and changing financial conditions. The EBC welcomes the Financial Services Agency's (FSA) initiatives towards better regulation and hopes that they will move Japanese regulation forward on this basis.

The EBC has in previous White Papers repeatedly drawn attention to Japan Post and the preferential treatment it receives. We have seen some changes during the last year; however although Minister for Financial Services Aso has said publically that Japan Post Insurance (JPI) will not introduce any new products, very little has changed legally to put JPI and private insurers on an equal footing. The EBC repeats its position that JPI should fall under the same rules as private insurers and that there should be more transparency as regards JPI's access to and relationship with Japan Post's network. The EBC is following with interest recent developments regarding business alliances between JPI and private insurers. However, the EBC wants to clearly point out that this does not completely resolve the issue and that it is vital for the Government of Japan to comply with its obligations under the WTO General Agreement on Trade in Services (GATS).

In response to the global financial crisis, the Financial Stability Board (FSB) and the International Association of Insurance Supervisors (IAIS) embarked on efforts to establish a broader regulatory regime for insurers considered systemically important and those considered internationally active. The FSB/IAIS are advocating that such insurance companies maintain certain minimum capital requirements, adopt a market-based solvency measurement methodology such as Solvency II, implement certain risk management strategies, and develop resolution plans amongst other measures. Additionally, they are proposing that national insurance regulatory bodies increase information sharing with other regulators across borders. As the regulator of Japan's financial market, the FSA would need to adopt many of the proposed policy measures before they could become effective in Japan.

We also believe that a permanent, post-funded scheme should be established for the Policyholder Protection Corporation (PPC). Appropriate handling of issues, such as the way Japan Post is privatised, bringing mutual aid cooperatives (*Kyosai*) into the insurance framework, streamlining the product approval process, and clear and consistent application of rules and regulations, would contribute to Japan's recovery from the financial crisis. This would also benefit the domestic financial services industry, Japanese consumers and Japan's ability to retain foreign investment.

The FSA product approval process is overly lengthy and FSA availability is limited. This results in product development delays and makes effective planning difficult. Approvals, when granted, are not flexible enough for the development of new products and features that are sensitive to volatile capital markets, particularly in response to the financial crisis. The EU-Japan FTA/EPA should eliminate all of these problems and contain common rules on competition and regulation to ensure transparent, fair and equal rules for all issuers of insurance. Furthermore, the agreement should include common rules for solvency calculations using market-based techniques based on Solvency II, and common rules for improving the transparency and predictability of regulations using a risk-focused approach.

Key Issues and Recommendations

■ Japan Post reform

Yearly status report: some progress. With the introduction of the bill on postal reform, JPI has been given preferential treatment that is not extended to other market players. The EBC regrets this situation as it leads not only to distorted competition, but also to a further expansion of what is already the world's largest financial institution. JPI has already indicated an interest in expanding its product portfolio. As a signatory to the WTO General Agreement on Trade in Services (GATS), the Government of Japan is obliged to ensure all market players enjoy equal treatment.

Recommendations:

- The Government of Japan should establish a level playing field before JPI is allowed to introduce new products.
- The Government of Japan should adhere to its commitments made under the GATS.

■ Kyosai

Yearly status report: no progress. *Kyosai* are mutual aid cooperatives providing insurance products. Under commitments made by the Government of Japan, these organisations should be governed by the same rules and regulations as foreign insurance companies, but this is currently not the case, as *kyosai* are not subject to the Insurance Business Law. Instead, different ministries regulate the various *kyosai* depending upon the sector in which the *kyosai* is active. For example, the Ministry of Agriculture, Forestry and Fisheries regulates the agricultural *kyosai*. The EBC would also like to point out that the original purpose of *kyosai* of supporting only a well-defined group like farmers or police officers has in many cases been abolished and today more or less any person, irrespective of affiliation, can sign up for a policy. For example, *Tomin kyosai* only requires the customer to live in Tokyo and the Central Union of Agricultural Cooperation (JA) can to a certain extent sell to non-JA members.

Recommendations:

- *Kyosai* should be brought under FSA supervision and be covered by the Insurance Business Law and should not be allowed to expand their businesses until such provisions are in place.
- *Kyosai* should only be allowed to sell insurance to the members of their own well-defined group.

■ Harmonisation with global solvency and other regulatory standards

Yearly status report: some progress. The EBC welcomes the update of the Solvency Margin methodology and positive statements made by the FSA on establishment over the medium-term of a market-based methodology, consistent with the principles of Solvency II. Further alignment of the local regulatory requirements with the approach of Solvency II is crucial for European insurers in Japan as it would enable them to use the same methodologies in all territories and better develop group-wide risk management strategies. Such a move would both encourage and reward improved risk management within insurance companies - a goal shared by the FSA and insurers – and hopefully reduce the overall regulatory reporting burden on insurers conducting business in multiple jurisdictions.

Recommendations:

- The Government of Japan should accelerate reforms aimed at attaining convergence between Japanese and global solvency standards by establishing a roadmap for convergence with Solvency II.
- The market-based Solvency Margin calculation methodology should be further aligned with Solvency II.
- The Government of Japan should fully participate in the development by the FSB/IAIS of enhanced regulatory measures for systemically important insurers and internationally active insurance groups.
- In adopting any or all of the FSB/IAIS proposed policy measures for the Japanese market, the Government of Japan should consider the burden that such risk management reporting and capital adequacy requirements could impose on these businesses and minimise any conflicting cross-border jurisdictional requirements.

■ Product approvals

Yearly status report: some progress. The FSA product approval process is overly lengthy and FSA's resources are limited. This results in product development delays and makes effective planning for insurance companies difficult. Furthermore, approvals, when granted, are not flexible enough to enable adaptation to ever-changing markets. In the long term, a "file-and-use" system should be introduced so that reputable companies do not have to start from scratch when introducing a product that is already on the market.

Recommendations:

- The FSA should improve its product approval process.
- The FSA should, furthermore, introduce a simplified approval system for products that are either fully or partially on the market already.

■ Bancassurance or bank sales channel

Yearly status report: some progress. It is common practice for insurance companies to use banks, and especially the physical network of the banks, to better market and sell various insurance policies. Although the market has been liberalised, some areas of the market cannot be accessed through this sales channel – notably sales of insurance to employees of companies of less than 50 employees where the company is a borrowing customer of the bank. While the EBC understands that the rationale behind this policy is to prevent banks from using their superior bargaining power to force clients to buy unnecessary or inappropriate insurance policies, we would like to point out that such behaviour is already prohibited by anti-trust law and the banks' codes of conduct. The EBC, furthermore, remains unaware of any major complaints from consumers about banks mis-selling insurance policies.

Recommendation:

- The FSA should further liberalise bancassurance to make it possible for banks to sell insurance to any company employee regardless of the relationship between the bank and the company.

■ Policyholder Protection Corporation (PPC)

Yearly status report: some progress. While the framework for PPC has long been discussed, very little has happened, and the system is still pre-funded. This situation exists even though the funds have not been used for several years. In addition, neither the total amount of the funds nor the annual assessment have been adjusted to better mirror the current more stable situation of the insurance market. The EBC would prefer a system that is post-funded to remove the risk of moral hazard among companies. We would also like to remind the authorities that some European insurers are already designated as Global Systemically Important Insurers (G-SIIs) with further requirements of enhanced supervision and higher loss absorption (HLA).

Recommendations:

- The FSA should amend PPC so that it becomes a post-funded system and at the same time introduce provisions for the system to better mirror the current market situation regarding the total funding and annual assessment.
- The EBC requests that the Japanese authorities take into consideration the situation of the G-SIIs when amending the PPC system.

Transportation & Communications

Airlines
Logistics & freight
Railways
Telecommunications carriers
Telecommunications equipment

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AIRLINES

Introduction

The Japanese airline travel industry is of global significance. About 5% of global traffic is connected to Japan, generating 10% of the global airline industry's revenues. Moreover, air transportation is critical to Japan as a catalyst for economic growth. However, Japan still ranks low in terms of air transport infrastructure quality, with the World Economic Forum ranking the country in 46th place, well behind several of Japan's neighbours. As a consequence of the catastrophic events of March 11th, 2011, the number of inbound travellers from Europe fell drastically and the reduction lasted for more than 15 months. Only by summer 2012 did travel volumes to and from Europe reach and surpass pre-disaster numbers. However, the substantial weakening of the yen, as well as the increase in consumption tax from April, 2014 mean there is now a significant risk of lower demand for leisure travel due to increased package tour prices.

The EBC urges the Government of Japan to continually work towards reducing charges at all Japanese airports, especially for those offering vital links to and from international markets. To date, the scope and pace of change have been disappointing. Airlines have long been required to pay prohibitive landing fees, navigation charges, airport terminal rent, airport terminal common user charges, and cargo handling fees as well as indirectly paying security fees, which should be borne by the Government and not by the airlines. According to the World Economic Forum's competitiveness ranking for Travel and Tourism, Japan ranks 133rd in the world in terms of airport and ticket charges (by way of comparison, the Republic of Korea ranks 26th). The EBC also notes that the new Narita Airport fee structure has not succeeded in producing any substantial cost reductions for users. While landing fees were lowered, other costs such as rents and baggage handling system fees were increased. We are closely following the construction and opening of the new terminal for Low Cost Carriers (LCC) and expect the cost structure for this terminal to be transparent and the complete cost to be borne by the terminal users, the LCC themselves.

Healthy competition is a pre-requisite for establishing a vibrant market driven by an economic rather than political rationale. While welcoming the opening up of Haneda Airport for intercontinental flights following completion of its new runway and international terminal in 2010, the EBC urges the Government to ensure that access is provided on equal terms to all carriers. Currently, only a limited window of operations (22:00hrs - 07:00hrs) is allocated to traffic to and from non-Asian destinations. Because flights from Europe are not permitted to land before 22:00 hrs, European carriers are denied the possibility of connecting with the domestic networks of their Japanese and Asian competitors, which do not operate domestic flights after 22:00hrs. While European carriers are restricted to serving the Tokyo metropolitan area at very inconvenient times, Japanese and Asian carriers can depart from and land in Japan at hours that easily allow them to be fed by and feed connections to practically every Japanese domestic airport. As of summer 2014, with the extension of Haneda Airport's international terminal and apron infrastructure, an additional 30,000 daytime slots (07:00hrs - 22:00hrs) will be available and assigned to airlines from major global and regional markets. European carriers are, however, concerned that payload restrictions or the lack of operational certification for certain aircraft types may limit competition for the widened access. Until a level playing field is established, Haneda Airport will not be able to play the role of a truly international hub as envisaged by the Government, and local cities will not benefit from the business potential that a fully fledged hub airport could provide.

The Government should also carefully consider the competition implications of the government-supported bail-out process and recapitalisation of Japan Airlines (JAL). The Enterprise Turnaround Initiative Corporation (ETIC) guaranteed various commercial transactions so that JAL could survive and be restructured in a controlled fashion. However, the protection umbrella organised by the Government, such as long-lasting tax breaks (9 years) and access to valuable slots at Haneda Airport, will distort competition not only within the Japanese airline industry, but also with European carriers which, due to the strict framework applied within EU bail-out legislation, do not benefit from any comparable advantages. In the interests of fair competition, JAL should not be allowed to conduct price dumping or capacity increases while receiving favourable government treatment. In particular, JAL should not be allocated more slots on European routes. EU competition law does not allow companies receiving restructuring support to increase production during a defined period of time.

Key Issues and Recommendations

■ High costs

Yearly status report: limited progress. The new Narita airport fee structure did not produce the expected substantial cost reduction for users – the lowering of landing fees was accompanied by an increase in rental and baggage handling system costs. The EBC believes that with improved profitability and a more streamlined process leading to lower costs, a permanent fee decrease should be feasible. In the meantime, Narita has announced giving discounts to airlines serving the Airport for the first time or increasing capacity. Such an approach would greatly disadvantage incumbent carriers, which have for years paid high prices. In addition, Japan's Airport Development Special Accounts have unfortunately had the effect of subsidising unprofitable airports by taxing major airports, which are the very facilities used by European airlines. The EBC believes this approach is not only unfair but also unsustainable and that, where there is little public value in operating an airport, it should either be closed or consolidated. If Narita is to remain competitive with other hubs in Asia, a new approach, leading to reductions in airport costs by as much as 50%, will be necessary. According to some media reports, the perimeter security control at Narita will be abolished at the end of fiscal year 2014 and replaced by a more efficient and passenger friendly process, which should lead to cost savings.

Recommendations:

- Fees have to be lowered if Japan is serious about becoming a true tourist destination in Asia.
- The competent authorities should ensure that no differentiation is made between new and incumbent airlines, and that the announced lower fee for LCCs is not subsidised by the mainline carriers.
- Savings achieved from the improved efficiency of perimeter security control at Narita must be shared with the airlines, which to date have had to absorb the cost within the given airport cost structure.
- Airport Development Special Accounts should be abolished to pave the way for the lowering of fees.

■ Airport infrastructure

Yearly status report: limited progress. At Haneda Airport, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has allocated some additional 30,000 new daytime slots to international routes (07:00hrs – 22:00hrs). The Government should consider the implications for competition between local airports and also between airlines. It is essential that all airlines should be able to use the airport on a commercially viable and practical basis. Haneda Airport cannot be considered to be a hub, if European airlines cannot use it to feed and defend traffic into/from the domestic Japanese network.

Recommendation:

- Japan should establish a plan for efficient use of all available airport infrastructure. Haneda Airport should be fully opened up to all international traffic, including flights to/from Europe, on a non-discriminatory basis. A reduction of night curfew hours at Narita Airport should be considered due to the now much lower noise levels of modern airplanes and their reduced environmental impact on the local community.

■ JAL Restructuring

Yearly status report: limited progress. The Government should carefully consider the competition implications of the government-supported bail-out process and recapitalisation of JAL. The EBC believes that proper surveillance should be carried out so that healthy competition and a level playing field are ensured. JAL should not be allowed to expand and conduct price dumping while receiving government assistance.

Recommendation:

- The Government of Japan should not allow JAL to distort competition by benefitting from long-term tax breaks as well as guaranteed loans. JAL should not be awarded a slot allocation at Haneda Airport for growth projects, especially for destinations to/from Europe, while it is still benefitting from generous government aid. Such a move would distort the level playing field for other operators on the route. EU competition law does not allow increased production during a defined time period for companies receiving restructuring support.

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LOGISTICS & FREIGHT

Introduction

European forwarding and express companies have successfully brought Japanese consumers the benefits of access to their worldwide logistics operations, but still face serious and significant regulatory challenges. In particular, they struggle with Japan's high cost base, inadequate infrastructure, very restricted aircraft operation time windows at international airports (especially in the Tokyo area), and rigid customs clearance procedures. They also have to deal with outdated restrictions on foreign-owned companies engaging in the domestic freight forwarding business, and unfair competition caused by differences in the rules and regulations applied to carriers even when providing exactly the same service, resulting in inefficiencies and higher prices for users. Heavy congestion in and around the port of Tokyo is also an issue, leading to low utilisation and long waiting times for bringing containers in and out of container yards in the port area.

Currently, Japan has nine separate customs areas and no central customs authority. A company is only allowed to lodge customs declarations at a clearance operation physically located within the jurisdiction of the responsible customs office. This makes it difficult for foreign logistics companies, which lack multiple regional offices in Japan, to expand their geographical coverage. Moreover, there are inconsistencies in administrative practices and interpretations between the various jurisdictions, causing uncertainty for logistics companies, importers and exporters. Within the Tokyo region there are two different customs territories, Yokohama and Tokyo, where Tokyo includes the Tokyo area, Narita and Baraki port and the rest of the region is the responsibility of Yokohama. The EBC believes there is a strong case for allowing companies more flexibility in choosing where to declare goods and for consolidating Tokyo and Yokohama ports as well as Osaka and Kobe ports. This should be done as a first step towards introducing a single national customs area. This would benefit not only foreign operators, but also small and medium-sized Japanese logistics companies.

Japan Post, which is currently restructuring, has plans to aggressively expand while it is still enjoying preferential regulatory treatment, thereby posing a serious threat to the functioning of the free market and the ability of competitors to provide services to the Japanese public. While the EBC recognises the need for a universal service obligation to meet certain socio-economic goals, Japan Post is benefitting from unfair competitive advantages in the express delivery market, where its Express Mail Service (EMS), a special value-added international express package, today accounts for more than 20% of the outbound express market. EMS is not subject to the strict regulations applied to private sector express services (as detailed on the following page), hence its expansion threatens further to distort competition and will negatively affect not only foreign private operators, but also Japanese companies and individuals. It is important to note that EMS is not part of the universal service in Europe, nor in the US. In Europe it is explicitly referred to as different from the universal postal service, while in the US it belongs to the category of "Competitive Services".

Companies expected the introduction of the Authorised Economic Operator (AEO) concept in Japan to lead to simplification of many of the transport and customs processes they need to undertake in order to provide their services. Unfortunately, the new system has missed this target: instead of streamlining the process, it has burdened companies with an increase in administrative tasks and compliance requirements in order to achieve AEO status. Many have reached the conclusion that, although beneficial in theory, the advantages of achieving AEO status in Japan have not justified the investment.

On the other hand, the EBC applauds the newly signed EU-Japan mutual recognition agreement on Authorised Economic Operators (AEO) and is very much looking forward to the practical result of this agreement. We believe that the EU-Japan FTA/EPA could further enhance trade by extending co-operation to additional customs areas. The FTA/EPA should also open up the sector by establishing equal treatment of Japanese and European operators, in particular eliminating the ban on foreign freight forwarders engaging directly in Japan's domestic air freight forwarding business.

Key Issues and Recommendations

■ Customs clearance and declaration

Yearly status report: no progress. Currently, declarations can only be lodged at a customs clearance operation physically located within the territory of the responsible customs office. Deregulation of customs jurisdictions, allowing remote filing of clearances at locations independent of the territory of the responsible customs office, would increase flexibility and improve capacity planning for customs brokerage operators. The current set-up makes it difficult for foreign logistics companies, and also small and medium-sized Japanese companies, to expand the reach and coverage of their customs clearance businesses. Administrative practices and interpretations vary considerably between the different customs territories in Japan, often causing problems and uncertainty for logistics companies and importers. Better alignment between local customs offices is of the utmost importance.

Recommendations:

The Government of Japan should:

- Allow companies freedom to choose the customs declaration location, independent of the territory of the responsible customs office.
- Enable greater flexibility in terms of where quarantine shipments can be checked. Checks carried out in special bonded warehouses should be facilitated.
- Remove the caps on customs clearance charges and allow free and fair pricing to be set by the market.
- Streamline the reporting and administration requirements of the various customs authorities to provide more standardised interpretation and application of customs rules and reporting requirements.
- Introduce a single national customs area, or as a first step, merge Tokyo and Yokohama ports, as well as Osaka and Kobe ports.

■ Level playing field with Japan Post's EMS

Yearly status report: no progress. Currently, Japan Post is only required to declare EMS packages to customs when the goods they contain exceed 200,000 yen in value, substantially higher than the level applied to equivalent packages handled by private sector operators. Additionally, the Parking Law is in practice not applied to EMS-carrying vehicles, although the National Police Agency has declared that EMS is subject to its provisions. EMS shipments containing materials such as quarantine-related goods, which are subject to control by various regulations (*tahourei*) other than the Customs Law, are not checked by government offices at the first port of entry (usually an airport), in stark contrast to the thorough checking of packages arriving with private operators.

Recommendations:

- The Government of Japan should ensure a level playing field by (1) applying the same threshold for customs declarations to both EMS and private express deliveries, (2) applying the Parking Law equally to all parties, and (3) ensuring equal rules for submitting advance cargo information.
- The Government of Japan should allow private express delivery companies to use their own facilities to clear quarantine-related goods.

■ Authorised Economic Operator (AEO)

Yearly status report: new issue. The current system of AEO has unfortunately not led to the simplifications that many operators had hoped for. On the contrary, in many cases the administrative burden has increased. The EBC seeks a system that gives companies a simplified process and extended powers to handle matters without the involvement of the authorities in every single case, provided that the operator can demonstrate sufficient control over the flow, and that a traceability mechanism is in place.

Recommendations:

- The AEO concept should focus more on offering simplifications, provided the operator meets the agreed criteria for tracing each product and adhering to the agreed process flow.
- The Government of Japan should introduce more benefits for imports handled by AEOs, including but not limited to:
 - ◇ Deregulating customs clearance beyond the local customs jurisdiction territories;
 - ◇ Reducing the physical examination of shipments.

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RAILWAYS

Introduction

Almost three years have passed since the Tohoku Earthquake, yet much remains to be rebuilt and progress is slow. Between March 2012 and mid-2013, only 100 km of railroad was restored, with 270 km still outstanding. Some rail-bound operations have been replaced by bus services, however the EBC Railways Committee believes that in rural areas the train station plays a vital role and an increased focus on a Bus Rapid Transit (BRT) system will weaken communications and communities alike. The EBC, with its particular expertise in urban planning and rail technology, believes that a Light Rail Transit (LRT) system should be introduced. This would be a strong symbol not only of the reconstruction, but also the revitalisation of the region.

The total value of rolling stock produced in Japan in 2012 was 172 billion yen, down 5.4% from the previous year. This figure includes new production, remodelling and repairs. Around 70% of the production was for the JR companies. The value of rolling stock imported from abroad was extremely low in comparison, amounting to only 60 million yen. The value of railway-related parts production in Japan in 2012 was 235 billion yen, while the value of imported parts was 22 billion yen. Although the Japanese market has decreased on an aggregated level and foreign penetration currently remains low, the EBC emphasises that Japan remains a large market with good potential for European manufacturers and service providers.

Part of the reason for negligible foreign penetration in the Japanese market is the strong position held by the operators, the JR companies in particular, which have traditionally only purchased products and solutions from manufacturers who develop them exclusively for Japanese buyers. This has created a situation where other products, even if tested and certified according to international standards, are not considered by Japanese operators without further extensive testing.

Nevertheless, since the Japanese railway companies are increasingly focussing on overseas markets, MLIT has set up a Railway Certification Center to certify products for those markets. In many instances, this testing corresponds to international standards. Although the current certification and testing programmes used by the Center have the objective of assisting Japanese railway-related manufacturers to export their products overseas, the EBC hopes that they will also foster an appreciation of international standards, testing and certification bodies in Japan. Currently there are no plans for Japanese operators and manufacturers to use the testing programmes in the domestic market to certify local and imported products: operators still have their own testing and certification schemes and do not accept overseas certification. However, we are encouraged to note that some market players have started to look to the EU for advanced technology and partners fitting their requirements and believe that it is now both logical and crucial for the Japanese Government and operators to recognise testing and certification carried out by European approved bodies.

Japanese manufacturers and operators frequently approach foreign markets in emerging economies with the backing of the Japan International Cooperation Agency (JICA). Depending on the conditions for the resulting aid, sometimes only Japanese companies or products can be used. Such tied aid is not used by European countries and the EBC believes that Japan should not exclude European manufacturers from aid-related projects. This subject could and should be discussed in the FTA/EPA negotiations.

The EBC believes that the EU-Japan FTA/EPA should enable Japan to work jointly with Europe to promote open integrated systems built on harmonised standards. Furthermore under the FTA/EPA, test data from internationally recognised certification bodies should be accepted without further delay and references from Europe should be fully recognised and accepted.

Since its inauguration, the EBC Railways Committee has developed close contacts not only with the Ministry of Land, Infrastructure, Transport and Tourism (MLIT), but also with related governmental organisations such as testing and standard-related bodies. The Committee is very pleased with the improved channels of communication with several Japanese operators and wishes to develop these further.

Key Issues and Recommendations

■ Introduction of open integrated railway systems

Yearly status report: limited progress. Product development in Japan is dominated by operators who appoint manufacturers to develop new products according to pre-set specifications within a closed system, instead of allowing manufacturers the freedom to find the most appropriate solution.

Recommendations:

- The Government of Japan should promote and encourage open integrated railway systems, in which operators set only the performance criteria, and the manufacturers develop and provide the solutions, as a way to boost competition in the domestic market and export prospects for Japanese manufacturers.
- The EBC would welcome continued dialogue and exchange of opinions on this theme with government officials, research institutes, the railway operators and industry.

■ Mutual recognition of testing and certification, and harmonisation of standards

Yearly status report: limited progress. In 2012, MLIT established the Railway Certification Center under the National Traffic Safety and Environment Laboratory. The objective of this certification body is to provide testing and certification to help Japanese railway-related manufacturers export their products overseas. There was considerable expectation in the EBC Railways Committee that additional changes would be made to support foreign suppliers and importers as well. However, over the past year we have not been able to find any common understanding on promoting harmonisation between Japanese operators, regulators and the EU railway community. On the contrary, there is a feeling that since the privatisation of Japan's national railways, the safety requirements of the operators have been drifting further apart. We believe it is crucial and mutually beneficial for the Japanese JR operators to work together with the EBC Railways Committee to define common requirements. With this important first step a roadmap could define how to move towards mutual recognition of testing and certification, and harmonisation of standards.

Recommendation:

- Establish a working group with the participation of the JR groups and other major Japanese operators to identify minimum common requirements acceptable to all operators.

■ GPA - definition of the operational safety clause and its scope

Yearly status report: progress. Japan and the EU are both signatories to the WTO's Plurilateral Agreement on Government Procurement (GPA). Within the framework of the agreement, Japan negotiated a specific clause applicable to transport (the operational safety clause), which stipulates that procurement related to the operational safety of transportation is excluded. In practice this means that the prescribed GPA procedures are rarely, if ever, followed in Japan's rail sector. The EBC regrets that this safety clause is used to avoid a proper tendering system which would give every supplier the chance to offer its products, irrespective of its country of origin.

Recommendations:

- Japan should publish a clear definition of the operational safety clause and its scope in order to enable all companies to meet or exceed the requirements.
- The EU and Japan should continue the positive discussion of this issue that has been undertaken under the auspices of the EU-Japan Scoping Exercise.

■ Tenders

Yearly status report: new issue. Japan has never had a system of tendering for railway-related projects. Part of the reason for this lies in its effective exclusion of the transport sector from the GPA (see above). The EBC, however, would like to commend JR East for its recent call for tenders for a signalling system. The EBC hopes that Japanese operators will start to use tendering procedures as the main method for procurement of railway-related products and services.

Recommendation:

- The Government of Japan should promote the use of tendering as this will improve competition in the Japanese market, leading to safer, cheaper and better products for Japanese operators, which in turn will benefit passengers in Japan. The EBC encourages other operators to follow the example set by JR East.

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TELECOMMUNICATIONS CARRIERS

Introduction

The global economy is increasingly dependent on access to well-functioning networks. Whilst Japan has developed one of the most sophisticated information infrastructures in the world, the EBC believes there are still some areas that can be improved.

The notion of creating an independent electronic communications regulator has been widely discussed in Japan, including in political debates. The EBC regards independence of the regulatory process to be good practice in order to promote decision-making that is objective, transparent and accountable, and to build trust and credibility within the industry in order for different viewpoints and interests, including economic, social, and political objectives to be duly considered. The EBC believes such independence should be reflected in the institutional organisation in Japan and in its system of checks and balances. The resulting regulator should, furthermore, report directly to the Japanese Parliament.

Whilst recognising that the Ministry of Internal Affairs and Communications (MIC) has made tremendous progress in advancing the Information and Communication Technology (ICT) industry, the EBC nevertheless believes there is a need for an oversight body with a majority of independent members and due transparency of its proceedings and decisions. This is particularly important in the light of Japan's transition to the model of equivalence, non-discrimination and functional separation. We believe that such a measure could provide more explicit assurances of fair treatment to customers, incumbents and competitors.

The EBC has long argued that ensuring fair competition is essential if Japan is to remain a vibrant telecom market. Creating an independent regulator is crucial, but only one of many elements that need to be put in place. There is also a need for better transparency in the cost mechanism for interconnection charges. Moreover, universal service obligations should reflect actual costs, thus helping to avoid unfair cross-subsidy. Japan has relatively high access prices compared to neighbouring East Asian countries so it is important that a much more holistic approach is taken in order to maximise competition in the market.

As large transfers of personal data between servers are becoming common and involve an increasing number of companies as well as administrations both as users and as providers, authorities are looking into how big data should be regulated. While by no means a new issue, the last couple of years have seen an immense increase in the volume of data. The EBC fully understands the need for regulating this field, emphasising, however, that any regulation should be designed so as to fulfil the security requirements, while avoiding placing companies under an excessive compliance burden. The EBC believes that it is of the utmost importance for there to be flexibility and pragmatism and for new rights and definitions to be clear. The process of formulating the regulations must be transparent and open to comments from outsiders. Special care should be taken regarding the issue of international transfers of information, so that companies can make full use of the advantages of cloud technologies. An appropriate balance should, therefore, be struck between protecting and informing consumers and providing the right environment for companies to conduct business. As such, it is crucial that authorities do not work in isolation, but constantly communicate with each other worldwide to learn from best practices.

The EBC Telecommunications Carriers Committee has high hopes of the benefits that an ambitious FTA/EPA between Japan and the EU can bring, and strongly believes that telecom issues should be covered, including detailed commitments and pro-competitive rules for the telecommunications and ICT services sector for business and end users. These commitments should go beyond those made under the WTO Basic Telecoms Agreement of 1998 and its annexed Reference Paper. They should, in particular, cover wholesale access regulation. The negotiations should also explore whether there is a case for enshrining EU-Japan ICT policy and regulatory principles in the Agreement, given the existence of EU-US and US-Japan ICT principles. It may also be instructive to consider if such broad principles can be agreed in future regulatory harmonisation in important hi-tech related areas, such as cloud computing, transborder data flows, data privacy, and cyber-security.

Key Issues and Recommendations

■ Institutional reform

Yearly status report: no progress. The EBC believes that it is inappropriate for the Government of Japan to act as both the regulator and a major shareholder in the Japanese telecommunications sector. Currently, however, MIC continues to enjoy wide-ranging statutory powers of intervention and control. The issue of independence was raised by the previous Government, but so far no discussion has taken place under the current Government. The EBC recommends the creation of an independent government committee as an independent regulatory authority, with a mandate to monitor regulation and business practice within the communications sector from a consumer perspective.

Recommendation:

- An independent, well-resourced and empowered telecommunications regulatory authority should be established with a pro-competitive mandate that measures its success in terms of a market that provides choice and enables the rapid introduction of innovative new services as well as reliable and cost-effective basic telecom/other services. To be independent, members should be selected from outside the Government and the committee should report directly to Parliament, and not to the MIC.

■ Data protection for big data

Yearly status report: new issue. With vast amounts of personal data being sent between servers daily, authorities have realised that there is a need to regulate this area. The EBC is keen to contribute to the policy debate, believing that any changes should be straightforward and practical. Regulation should strike a careful balance between protecting individual privacy and creating an environment that supports innovation of new products and services driving economic growth and employment in Japan.

Recommendations:

- New obligations on data processors should be clear and any definitions must provide clarity.
- The authorities should avoid overly complex regulation that could inadvertently lead to increased cost and so off-set the advantages of offering data processing.
- Any new regulation should also provide a balanced approach to minimise the inherent conflict between privacy for individuals and the need for companies to use information.
- Special focus is needed on international transfers of data to make certain that data flows are not “stopped” at the border, while at the same time introducing best practice to make certain that data are kept safe.

■ Fair competition

Yearly status report: some progress. MIC will start reviewing fair competition rules in 2014, having already finished its initial research and public comment procedure. There are many items on the agenda including crucial topics such as the functional separation of NTT. The EBC believes it is of utmost importance to follow fair competition principles based on global practices. These principles will ensure that future discussions on fair competition rules will be successful.

Recommendations:

- The Japanese Government should ensure the transparency and efficiency of the regulatory process, including providing adequate time for consultation.
- The Japanese Government should introduce open and simple licencing procedures with minimum service and regulatory obligations.
- Incumbent carriers should be obligated not to discriminate on price or other conditions between their own businesses and those of competitors and to provide suitably separated published accounts.
- There should be transparent control by the regulator of access to the radio frequency spectrum, to physical rights of way and to the numbering plan.
- There should be proactive regulatory oversight of the implementation of any schemes for “equal access” and number portability to support newcomers to the market.
- To help avoid unfair cross-subsidisation, operators with significant market power should keep transparent, publicly available, separate accounts.

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TELECOMMUNICATIONS EQUIPMENT

Introduction

The Information and Communications Technology (ICT) sector accounts for 14% of Japan's total industrial output, worth an estimated 13.9 trillion yen (2011 figures). Structural reforms under the Government of Japan's ICT Strategy have supported the introduction of high-speed, large-capacity ICT infrastructure, the lowering of communications costs, and the development of e-commerce and e-government. Internet access costs have decreased dramatically and access to broadband is now amongst the most developed in the world. In 2006, the e-Japan Strategy devised by the ICT Strategic Headquarters set out to further improve the country's hyper-speed network infrastructure, competition policy, e-commerce, and e-government, and in 2009 the same organisation set up the "i-Japan Strategy 2015" with the goal of providing broadband to everybody, everywhere and at any time. An additional goal is to improve health-care and education through ICT, as well as creating new industries. In June 2013, the Cabinet approved "the world's most advanced IT nation creation declaration" and with it intensified Japan's efforts to realise an IT-based society.

The EBC appreciates the opportunity to contribute to the Ministry of Internal Affairs and Communications' (MIC) policy committees as an official participant and respects the Government's overall commitment to an industry-led, global approach to standards and platform development. Important steps have been taken to facilitate the product approval process, firstly by signing an EU-Japan mutual recognition agreement (MRA) for telecommunications terminal equipment in 2001, and secondly by introducing a Supplier's Self Verification of Conformity (SVC) in 2004. Despite these significant achievements, however, implementation to date has been disappointing. The number of accredited testing bodies designated under the MRA remains low and the SVC still applies only to wired telecommunications terminals, with limited application to wireless/radio equipment. Although some additional products have been added to its scope, many products are still not covered by the SVC.

In the area of spectrum allocation, in 2012 Japan allocated both the 700 and 900 MHz bands for mobile telephony by a process requiring each applicant company to submit information on its planned use of the bands in terms of investments in both infrastructure and availability to consumers, upgrades and so on. The EBC is pleased to see that the bands mirror mobile telephony best practice in other large markets, such as the EU and the US.

There are approximately 6.4 billion mobile subscriptions globally and 1.7 billion of these are connected to mobile broadband, with overall mobile data traffic doubling each year. In a mature market like Japan, with advanced data services and LTE introduction, smartphone penetration is about 50% and is driving mobile broadband growth and a projected traffic usage of 10 GB/month per user in 2020. There is a paradigm shift from a traditional telecom model to a networked society model, where applications and users can demand variable speeds and latencies. The various applications used on smartphones, such as video and social networks, place different demands on the network. Mobile user expectations are now changing and studies have shown that a 100 ms improvement in delay can lead to a 1% increase in revenue for an e-commerce website. Smartphone users in Japan complain about slow and failed downloads/uploads of content (e.g. web pages) more than streaming problems and approximately 37% of service problems might be related to overall network speed. Network Neutrality essentially encompasses the limits placed on an operator's ability to manage its network, including how the operator is allowed to package and control services sold to end users, and regulatory clarification is required.

The EBC believes that to facilitate trade between the EU and Japan, the current duplication of product certifications for telecommunications equipment sold on both the European and Japanese markets should be eliminated. The FTA/EPA between the EU and Japan should establish true mutual acceptance in which telecommunications equipment products certified for either the European or Japanese market would automatically be approved in the other. The current framework provides only for recognised certification organisations to test for both markets. Mutual acceptance of technical standards and certifications for all telecommunications equipment would be a natural part of the FTA/EPA.

Key Issues and Recommendations

■ Establishing common technical standards and certification procedures

Yearly status report: some progress. The EU and Japan maintain different technical standards for the same products, which, although not substantially different in their detail, lead to double testing and certification for manufacturers. The current EU-Japan Mutual Recognition Agreement provides only for recognised certification organisations to test for both markets. The Japanese certification process is also different from that of Europe. The EBC welcomed the introduction of SVC by the Government of Japan at the beginning of 2004, which is similar to the Suppliers' Declaration of Conformity (SDoC) introduced in Europe. However, the EBC is disappointed that this system is limited to wired telecommunications terminals in general and that the application has not been expanded to include other telecommunications equipment, except for WiFi functions in mobile terminals (thus continuing to exclude radio base stations for mobile networks).

Recommendations:

- The EU and Japan should mutually accept each other's technical standards and certifications for telecommunications equipment. This could be achieved through the FTA/EPA.
- SDoCs issued by European producers should be accepted in Japan without any additional testing or administrative requirements, not only for wired terminals, but also for specified radio equipment.
- Application of SVC should be expanded to all equipment in the category of "Specified Radio Equipment".

■ Harmonisation of spectrum for IMT (IMT-2000 and IMT-Advanced)

Yearly status report: some progress. The EBC acknowledges that the Government of Japan has been active in trying to identify a globally harmonised spectrum for International Mobile Telecommunications (IMT) systems. This would bring enormous benefits to the industry and consumers by eliminating the need to develop local variations of new telecommunications equipment. Therefore, the EBC was pleased to note that in 2010, MIC presented a plan to allocate the 300 MHz band to wireless broadband including IMT by 2015, and awarded licences for the 700 MHz and 900 MHz bands in 2012 with the possibility of achieving harmonised spectrum allocation and arrangement for IMT systems. The EBC also notes that MIC has completed a study report on the technical requirements for IMT-advanced especially in the band between 3,400 MHz and 3,600 MHz.

Recommendations:

- The Government of Japan should work jointly with other governments to achieve a globally harmonised spectrum allocation for IMT systems, in line with the findings of the World Radio Communication Conference in 2007. This should include the bands of 700 MHz, 2,300 MHz and 3,400-3,600 MHz.
- The Government of Japan should work actively in accordance with agenda item 1.1 of the World Radio Communication Conference in 2015, in order to identify new harmonised spectrum for IMT systems.

■ Mobile Network Management

Yearly status report: new issue. Japan is a mature and advanced market for mobile broadband and projected traffic is 10 GB/month per user in 2020. The various applications on smartphones, such as video and social networks, put different demands on mobile networks. Network Neutrality essentially encompasses the limits placed on an operator's ability to manage its network, including how the operator is allowed to package and control services sold to end users. The EBC recognises that the Government of Japan looked into this issue in a 2007 study, "Working Group on Network Neutrality" and recommended that a mobile operator manages end users generating larger traffic over a certain limit, while ensuring an open, unrestricted and accessible Internet experience for all users. Recent technical developments, however, make it possible for an operator to manage its network in a better way in order to use the network resource efficiently and to offer end users differentiated services, but the EBC notes that the recommendation in the 2007 guidelines does not mirror this development.

Recommendations:

- The Government of Japan should provide regulatory clarification on Network Neutrality.
- The Government should review its policy on Network Neutrality, considering the recent technical developments in the mobile network, so that mobile operators can take advantage of the latest technologies in network management for better use of resources and provision of differentiated services.

Health Science

Animal health
Medical diagnostics
Medical equipment
Pharmaceuticals
Vaccines
Cosmetics & quasi-drugs

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ANIMAL HEALTH

Introduction

The animal health product market in Japan is worth approximately 100 billion yen, and ranks 6th in the world. In the past, it has been an important market for European companies. Japan has, however, lost its attractiveness in recent years due to low growth rates and the high cost of doing business. The Japanese animal health market is, like that of Europe or the USA, highly regulated. Japan belongs to the trilateral (EU-Japan-USA) programme of the VICH (International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products), a veterinary equivalent of the International Conference on Harmonisation (ICH) for human medicine, which aims to harmonise registration requirements for animal health products at the global level. This has helped to some extent in the reduction of registration costs for globally developed products. There are, however, still some requirements that are unique to Japan and often prevent or delay access to innovative and useful animal health products for animal owners, veterinarians and consumers. This is unnecessary, since these products will have gone through a rigorous review process in Europe and the USA prior to registration thus assuring their efficacy, safety and quality. Japan's regulatory requirements for innovative veterinary medicinal products based on biotechnology are especially stringent and, therefore, products readily available in Europe are often not available here. More rapid access to new animal vaccines and medicines is necessary for the Japanese livestock industry to remain competitive with foreign producers. This issue will become more acute in the future should Japan's participation in the EU-Japan FTA/EPA and the Trans-Pacific Partnership free trade zone (TPP) require the elimination or reduction of tariffs and subsidies for animal agriculture. If producers in Japan cannot maintain competitiveness, Japan will continue to become increasingly dependent on imported animal products.

Marketing authorisation of a veterinary medicinal product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal drug intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labour and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process for food-producing animal health products is complex and often inefficient, lacking good coordination and taking a very long time before a product becomes available to livestock producers.

In the case of biological products, most of the specification items are unique to Japan, including the requirement for a serological potency test on live vaccines. Product specifications have to be established purely for the Japanese market and each batch of vaccine has to be released based on these unique specifications, often requiring duplicate testing at the manufacturing site.

While studies conducted overseas under Good Laboratory Practice or Good Clinical Practice are accepted by MAFF for inclusion in the registration dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. This means that any overseas production facilities involved in the manufacture of veterinary medicinal products for importation into Japan, whether those products are active pharmaceutical ingredients or final products, have to be accredited by MAFF, even though their GMP status is authorised by European authorities. This process involves a large amount of redundant administrative paperwork.

For the last few years, MAFF has been implementing various measures to improve the predictability, quality, and speed of the registration process and these are improving to some extent, but there are still delays in the review process for some product segments. The EU-Japan FTA/EPA should aim for mutual recognition of European and Japanese marketing authorisations for veterinary products, starting with mutual recognition of GMP certification for veterinary medicines.

Key Issues and Recommendations

■ Product approvals

Yearly status report: limited progress. Products already approved in the EU, especially veterinary biological products, have to undergo further rigorous controls and tests before being approved in Japan. Requirements for additional animal testing without an obvious scientific rationale create serious animal welfare concerns. The applicant is still required to answer questions of little relevance to the safety and efficacy of the product. Since three different regulatory authorities (MAFF, FSC and MHLW) are involved, and part of the registration is not globally harmonised, the registration of food-producing animal products can take an extremely long time. For example, the withholding period prior to shipment for the slaughter of food-producing animals vaccinated with an oil-adjuvanted vaccine is significantly longer in Japan compared with reference countries. The long withholding period, which is a burden for producers, means that some innovative and useful vaccines used in the EU or the USA cannot be used practically in Japan.

Recommendations:

- The Government of Japan should use all measures available to speed up product approvals, including mutual recognition of product registration schemes, and fully harmonise domestic regulations with international practices. VICH guidelines should completely replace obsolete regional guidelines.
- In view of animal welfare concerns, requirements for additional animal studies should be minimised where similar studies are already available in other countries.
- Reviews of food animal products by MAFF, MHLW and FSC should be conducted in parallel to shorten the overall review period for veterinary medicinal products for food-producing animals.

■ Seed-lot system and national assay of vaccines

Yearly status report: progress. The seed-lot system enables the production of vaccines using a working seed virus/bacteria derived from an established master seed virus/bacteria. Thanks to the MAFF initiative to introduce the seed-lot system, some animal vaccines no longer require a national assay for batch release. However, some European vaccines cannot enjoy this benefit due to additional unique testing requirements, such as in-process testing that does not exist in the internationally recognised seed-lot system. Japan requires an inactivation test on the finished product only for imported inactivated vaccines and not for similar domestically produced inactivated vaccines, thereby creating a discriminatory non-tariff barrier to trade. Despite the fact that the safety of vaccines for dogs and cats is tested in the target animals, an Abnormal Toxicity Test using laboratory animals is required, which raises animal welfare concerns.

Recommendations:

- Requirements for eligibility to be included in the seed-lot system should be aligned with internationally recognised requirements, and no new unique-to-Japan requirements should be added.
- The requirement for an inactivation test on the finished product for inactivated vaccines should be eliminated.
- The requirement for an Abnormal Toxicity Test on vaccines for dogs and cats should be eliminated.
- Recombinant vaccines should also be eligible for inclusion in the seed-lot system.

■ MAFF/NVAL proposed action items

Yearly status report: new issue. On December 3, 2012, MAFF and NVAL (National Veterinary Assay Laboratory) presented to the Japan Veterinary Products Association Committee on Technical Issues and Regulatory Affairs a list of ten policy change action items targeted as measures to improve marketing authorisation procedures.

Recommendations:

- Although, in the opinion of the EBC, this list does not comprehensively represent all of the required reform areas, we support this initiative and request regulators to continue to identify additional reform opportunities. Further, we request MAFF and the NVAL to consult closely with the industry before any detailed policy change occurs to ensure harmonisation with similar policy in other major countries.

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MEDICAL DIAGNOSTICS

Introduction

Healthcare in Japan suffers from the fact that the social security system is under increasing stress from the effects of an ageing society, reduced birth rate, and burgeoning national healthcare costs. To remedy this situation, the Japanese Government needs to initiate institutional reforms to the way the system operates while also re-evaluating the purpose of the system itself. In particular, given the current move toward enhancing the quality of medical care and optimising medical costs, a serious discussion is needed on the value and role of medical diagnostics. It is crucial that both medical care providers and medical system operators properly understand and evaluate the major role played by medical diagnostics in medical care, so that the full contribution of diagnostics to medicine can be realised.

Since 2007, the problems, challenges and future direction of the reimbursement system for medical diagnostics have been under discussion. Research papers on the topic have been published, and proposals and recommendations have been made at study sessions on medical diagnostics and at periodic meetings on the medical reimbursement system conducted jointly by the Japanese Promotion Council for Laboratory Testing (JPCLT), the *in vitro* diagnostic (IVD) drug industry associations, and the Ministry of Health, Labour and Welfare. As a result, the Central Social Insurance Medical Council (*Chuikyo*) has now recognised that IVDs are essential for diagnosis and treatment, and declared that the improvement of their quality and prompt availability are crucial issues. In line with this declaration, the Council concluded that priority should be given to evaluating the quality of IVDs. The EBC appreciates the fact that these findings were reflected in the revision of IVD fees in the three most recent reimbursement price revisions, in 2008, 2010 and 2012.

Medical diagnostics provide 70% of the information required for deciding on a treatment strategy, and the costs of such diagnostics amount to about 4% of the total healthcare cost. These facts demonstrate both the role and importance of medical diagnostics in providing the necessary information for medical care to progress from prediction to diagnosis, treatment and monitoring. If new applications for medical diagnostics are to be discovered, it is vital to understand the relationship between the value they can add and the medical reimbursement system, as well as to create an environment where appropriate diagnostics are available at the appropriate time and place at an appropriate fee. Both the public and private sectors need to start in-depth discussions on this important issue, so that the quality of healthcare and patients' quality of life can be improved.

Medical diagnostics are still mostly used in Japan to treat and monitor patients in medical institutions. Yet their role could be expanded to include early detection of risk factors and the prevention of disease. Doing so would reduce healthcare costs and patient anxiety and would be in line with national healthcare strategy, which holds that Japan's future medical system should emphasise not only treatment, but also prevention, and which also promotes health examinations and preventive medicine.

The development of personalised treatment depends not only on development of the primary drug itself, but also on the development from an early stage of companion diagnostics to predict the effectiveness and side effects of the drug. Development of companion diagnostics, an associated approval process and relevant reimbursement system are all currently under discussion, in response to requests from industry organisations. The EBC believes a system should be set up promptly to enable widespread personalised treatment in Japan. Streamlining and reform of the current system will be essential for maintaining and improving the quality of medical diagnostics and medical care. Other major improvements needed to enhance the quality of medicine and deliver the latest medical care to patients include providing prompt access to new IVDs and setting reimbursement fees for IVDs based on their latest clinical value.

The EBC Medical Diagnostics Committee continues to advocate the value of medical diagnostics in cooperation with the JPCLT and other IVD industry groups.

Key Issues and Recommendations

■ Quick access to new IVDs

Yearly status report: slight progress. The introduction of a ministerial authorisation system, third-party certification and a self-certification system intended for risk classification and reinforced safety measures in the 2005 revision of the Pharmaceutical Affairs Law (PAL) were important steps in the right direction, but these measures still fall short of what is needed to ensure quick access to new IVDs. Risk classification methodologies and data requirements unique to Japan make the application and review process technically slow and, in some cases, redundant. In recent years, many product approvals have been substantially delayed, a situation that should be remedied immediately. The EBC expects the 2013 PAL revision to better reflect the characteristics of IVDs.

Recommendations:

- The Government of Japan should introduce the expedited review programme already used for medical equipment for use with IVDs, and periodically review the performance of the process from application through to approval of the product. This will ensure prompt access by the medical sector to the latest high-value clinical features of new products and enhance their contribution to healthcare.
- To make the product approval process more efficient, the EU and Japan should accept products already certified for either market as being equivalent to products certified in their own domestic market.
- The Government of Japan should ensure that simultaneous approval of companion diagnostics and their corresponding drugs, achieved in 2012, will continue in future.

■ Reimbursement system based on clinical value

Yearly status report: progress. The EBC welcomed the national health insurance reviews in 2008, 2010 and 2012 through which the reimbursement of IVD examinations was improved, following greater recognition of medical diagnostics by the Japanese Government. However, the Government still needs to reflect the full value of medical diagnostics and their contribution to healthcare in the reimbursement system if it is to create a competitive market of interest to European and Japanese manufacturers. The Government should also review the current process of insurance coverage so that the level of reimbursement reflects the added value (enhanced clinical significance and convenience) provided by improved methods. The current system discourages generational change and renewal through its lack of incentives to develop innovative new products: diagnostic reagents and procedures of the previous generation are reimbursed at the same level as more clinically useful diagnostic reagents. Preventive examinations and stratified examinations should also be reflected in the reimbursement system. Finally, it is also necessary to review problems found in the current scheme of reimbursement amounts for IVD examinations and results, to achieve adequate distribution.

Recommendations:

- The current process of applying for insurance coverage should be revised, such that improved methods with enhanced clinical significance and convenience are awarded reimbursements that reflect their added value, rather than the same reimbursement as the equivalent item from the previous generation.
- A periodic (for instance, every five years) performance assessment system should be introduced and administered by a third party to evaluate the performance of products already on the market, thus paving the way for products that do not necessarily have high clinical usefulness to be withdrawn. This would mean patients would receive examinations using the latest products, eventually reducing re-examinations due to misdiagnoses, cutting wasteful costs, and improving the quality of life for patients.
- The reimbursement amounts for medical diagnostics (IVD examinations) should better reflect their clinical value, based on differences in quality (accuracy, specificity, laboratory certification), speed (emergency response, urgent tests for out-patients), and contribution to comprehensive patient care (infection control, risk management, qualitative indications).
- The amount of reimbursement should serve as an incentive for the development of high value-added companion diagnostics for use with certain drugs.
- The current scheme of reimbursement for and evaluations of IVD examinations should be reviewed. Examination fees should, at the very least, be kept at the present level to reflect the value and role of in-hospital examinations and any additional amounts should be reviewed according to the IVD examinations.

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MEDICAL EQUIPMENT

Introduction

Healthcare in Japan is generally of a high standard, as might be expected in a country enjoying the highest average life expectancy in the world and one of the lowest infant mortality rates. In 2012, the national cost of medical care reached 38.4 trillion yen, up by 1.7% from the previous year, reflecting a society that is ageing faster than others in the world and placing increasing demands on health services. Accordingly, in addition to solving healthcare financing problems, it is important for Japan to build a scheme that will extend healthy life expectancy and enable daily life without restrictions, by offering opportunities for high-quality medical care (prevention of diseases, early diagnosis and early treatment). Wider use of innovative, efficient medical equipment in Japan would not only offer individual patients a substantially higher quality of life, but should also be considered an investment, reducing total expenditure on medical care over time and lengthening healthy lifespans.

Many Japanese regulations and processes differ from international standards. Such unique requirements mean that European manufacturers must devote extra resources, money and time to additional tests if they wish to introduce their medical equipment to the Japanese market. To help remedy this situation, the EBC has long called for international alignment of the Japanese system of good clinical practice (GCP), and quality management system (QMS). Japan's current reimbursement system also raises concerns because it fails to fully evaluate the innovation of medical equipment and so many European manufacturers are discouraged from launching their products on the Japanese market, depriving patients of access to the latest technologies and treatments.

In 2013 the EBC, jointly with the American Chamber of Commerce in Japan (ACCIJ), released the ACCIJ-EBC Health Policy White Paper 2013, offering 36 proposals for a new approach to health policy in Japan. Implementing these proposals would represent an important first step for Japan to change its health policy to emphasise prevention and early detection of disease. Such a policy shift would not only improve the prognosis for patients and save lives, but also improve the cost effectiveness and labour productivity of medical care, enabling Japan to meet the challenge of an ageing society with limited resources.

The negotiations for an EU-Japan FTA started in April 2013. In the medical equipment field, the EBC believes the Japanese Government should establish an environment that allows European medical equipment to be delivered smoothly to patients in Japan and has, therefore, proposed the lifting of non-tariff barriers (NTBs). The proposal includes, among others, "Clinical evaluation and international alignment of QMS," which has long been advocated by the EBC Medical Equipment Committee.

The Japanese Government considers the medical field as one of the important themes of its new growth strategy and in June 2013 announced its "Japan Revitalization Strategy," "Healthcare and Medical Strategy" and "Report on Promotion of Regulatory Reform." The Healthcare and Medical Strategy initiatives include the sub-topics of "Revision of Pharmaceutical Affairs Law Considering the Characteristics of Regenerative Medicine and Medical Equipment, and Legal Action to be Taken to Ensure Safety of Regenerative Medicine Based on the Law for Securing the Safety of Regenerative Medicine and Others," "Research and Active Practicing of Evaluation of the Effectiveness and Safety of Pharmaceuticals and Medical Equipment Utilising Emerging Technologies" and "MPDA Reinforcement including Improvement of Pharmaceutical Strategy Consultation and Enrichment of Examination and Safety Measures." The "Report on the Promotion of Regulatory Reform" also covers the topics of "Review of the Certification System Based on the Characteristics of Medical Equipment," "Systematic Establishment of a Certification Standard for Medical Equipment," "Insurance System with Increased Incentives for the Development of Medical Equipment" and "Review of the Adequacy of Applying the Electric Appliance Safety Law to Components Built into Electric Medical Equipment." Proposals made by the EBC Medical Equipment Committee are extensively addressed in these reports. The EBC will carefully monitor the progress and eventual realisation of these initiatives while continuing to work with the Japanese Government to implement the project as planned.

B.Braun Aesculap Japan	Maquet Japan
Biotronik Japan	Molnlycke Health Care
Coloplast	Nippon Becton Dickinson
Dentsply IH	Nippon BXI
Dornier MedTech Japan	Nobel Biocare Japan
Draeger Medical Japan	Otto Bock Japan
Edaptechnomed	Philips Electronics Japan
Elekta	Radiometer
Gambro	Siemens Japan
Intuitive Surgical.	Smith & Nephew Wound Management
Japan Lifeline	Sorin Group Japan
Japan MDC	Teijin Pharma
JIMRO	TKB
Laerdal Medical Japan	VitalAire Japan
Lima Japan	Wako Shoji

Key Issues and Recommendations

■ Revision of Pharmaceutical Affairs Law

Yearly status report: new issue. The Pharmaceutical Affairs Law (PAL) will be revised such that medical equipment will be treated separately from pharmaceuticals, which has not been the case under the existing law.

Recommendation:

- The Government of Japan should ensure that “operation of the system fully considering the characteristics of medical equipment” will be realised as expected under the revised law.

■ Clinical evaluation

Yearly status report: slight progress. The alignment of Japan’s GCP with ISO14155 has advanced the process of clinical evaluation considerably. However, although the clinical evaluation standards themselves are now aligned, some issues still remain. For example: (1) many more products are subject to testing in Japan than in Europe and the US; (2) Japan differs from the EU and US in the regulatory treatment of applications aimed at extending the use of approved products to additional diseases; and (3) clinical tests are often required for equipment that has only been modified or improved. Even after approval, medical equipment is still subject to surveys on its actual use, to further review and to other regulatory requirements that do not exist in the EU or US. This increases costs, resulting in fewer European products being introduced in Japan.

Recommendation:

- The Government of Japan should expand the range of products for which clinical tests are not required, building on the systems in Europe and the US. Japanese authorities should evaluate the clinical records of actual use and relevant clinical literature in order to avoid (or substantially reduce) further unnecessary clinical testing when products are already available on the EU or US market.

■ Mutual recognition and alignment of QMS

Yearly status report: slight progress. QMS for medical equipment is a system to control the entire process of products from the early stages of design and development to production, safety in the market and obsolescence. However, the QMS compliance survey in Japan focuses only on the production line of manufacturing sites and is more applicable to drugs. As a result, excessive and unnecessary QMS compliance investigations have to be conducted on medical equipment in Japan, creating a huge administrative burden, increased costs, and significant delays in market introduction. A streamlined QMS investigation has been proposed in conjunction with the revision of PAL, but it is unclear how it will be achieved.

Recommendation:

- The Government of Japan should recognise that QMS audits conducted by competent third parties (notified bodies) in the EU provide sufficient evidence of compliance with quality management system requirements. Accordingly, the EBC recommends that 1) the Government recognises the ISO13485 investigation methods of the EU and adopts a similar approach in its own examinations of the quality systems of manufacturing sites, and 2) qualification requirements for QMS supervisors should be aligned with ISO17021.

■ Reimbursement prices

Yearly status report: some progress. The major problem of the current reimbursement scheme is that, due to the lack of marketability of medical equipment and the unpredictability of reimbursement prices, manufacturers back away from investing in innovation. The reimbursement prices of some new medical equipment products are set below average prices in foreign countries. The current scheme should be reviewed to promote the development of new and innovative products. The approach to homecare medical systems also has much room for improvement.

Recommendations:

- Create a more detailed division of functions into subcategories, introduce multiple prices for same-category materials, abolish the re-pricing system, and enable predictability of applications for C2 medical techniques.
- Regarding home medical equipment, there should be adequate evaluation of innovation and proper recognition of equipment and materials costs where the home-care patient does not attend hospital.
- There should be continuing evaluation of the system to ensure the swift introduction of products with appropriate insurance coverage.

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PHARMACEUTICALS

Introduction

Japan's national expenditure on medical care in fiscal year 2012 was an estimated 38.4 trillion yen, or on average 301,000 yen per person, up 1.7% from the previous year. Whereas average expenditure on persons below 70 years of age was 181,000 yen, for those aged 70 or older, it was as much as 804,000 yen, approximately 4.4 times greater. The proportion of total medical care expenses accounted for by drug expenditure has remained relatively stable over the last 10 years at about 20%. Regular biennial drug price reductions and government action to reduce costs through promotion of generic drugs have helped to control relative growth in drug expenditure in spite of an ageing population. In April 2013, the Government of Japan announced its "Roadmap to Promote the Use of Generics", and intends to increase the share of generics among replaceable drugs from approximately 45% in March 2013 to 60% in March 2018.

A new drug pricing policy was introduced on a trial basis in 2010 to promote the development of new drugs and eliminate unapproved off-label use. Since then, early data from European R&D-based pharmaceutical companies indicate that the number of new drug development projects and investment in Japan are beginning to increase. The new system adequately recognises the value of innovation, and should be made permanent to ensure continued investment in Japan's drug development, which is exposed to fierce global competition. Equally, consideration should be given to eliminating arbitrary re-pricing measures that cut the prices of drugs whose sales significantly exceed initial expectations (as well as the prices of comparable drugs), and thereby undermine efforts to promote innovation.

Despite government policies aiming to promote new drug development, patient access to innovative drugs is hindered by the blanket restriction of prescription lengths to a maximum of 14 days for all new drugs in the first year after their launch. Patients are thus required to visit hospital once every two weeks to obtain a new prescription, which imposes a significant burden on them. Until this restriction is lifted, the adoption and prescription of new drugs will continue to be delayed in medical institutions employing many specialised physicians. This also delays patient access to the latest drug therapies that are already in extensive use abroad. Although the period in Japan between the approval of drugs and their reimbursement is the shortest in the world, and the drug lag is gradually decreasing thanks to recent improvements in the approval and examination process, a review of the restriction on the prescription period is not even on the agenda. Originally introduced in 1957 as a means of moderating health-care costs, the restriction subsequently developed into a uniquely Japanese approach to safeguarding public safety by limiting the use of new drugs with little track record. However, the safety of new drugs in Japan is now underpinned by the post-marketing surveillance system, which is one of the most advanced in the world. Moreover, in fiscal year 2013, a Risk Management Plan (RMP) was introduced to comprehensively examine individual new drugs in the examination process and to further improve the current surveillance system. Accordingly, EFPIA and the EBC believe the restriction of prescription lengths for all new drugs, without exception, to a maximum of 14 days should be reviewed.

Japanese Good Clinical Practice (GCP) in clinical trials used to differ in many aspects from global standards, but is now steadily being aligned with them, including through revisions made in December 2012. However, there has been no progress in extending the scope of the existing Mutual Recognition Agreement (MRA) for EU and Japanese Good Manufacturing Practice (GMP). The current limitation of the MRA to solid oral preparations leads to duplicate trials and inspections for all other products, incurring additional costs for the industry and ultimately the healthcare system. EFPIA and the EBC call on the EU and Japan to work together to eliminate such unnecessary costs.

The first Policy Dialogue between the current Government and Industry on the Creation of Innovative Pharmaceuticals and Medical Devices was held in May 2013. The format and rarity of such interaction are indicative of the need for more regular and substantive discussions on the future vision for the pharmaceutical industry. Moreover, following the decision to raise consumption tax from 2014 as part of the Government's "Comprehensive Reform of Social Security and Tax", specific measures in respect of social security, including medical care, need clarification. Moving the debate from pricing to funding of the healthcare system should become a priority for the Japanese Government. EFPIA and EBC members are ready and willing to contribute to this debate.

EFPIA Japan Member Companies

Abbott Japan	Guerbet Japan
Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Baxter	Lundbeck Japan
Bayer Yakuhin	Merck Serono
Bracco-Eisai	Nihon Servier
Chugai Pharmaceutical	Nippon Boehringer Ingelheim
CSL Behring	Novartis Pharma
Ferring Pharmaceuticals	Novo Nordisk Pharma
Galderma	Sanofi
GE Healthcare Japan	Shire Japan
GlaxoSmithKline	UCB Japan

Key Issues and Recommendations

■ National Health Insurance drug pricing system

Yearly status report: slight progress. In 2010, a new National Health Insurance (NHI) drug pricing system was introduced on a trial basis to promote the development of new drugs and eliminate unapproved off-label use. The system eases the rate at which the prices of qualifying drugs are periodically reduced and allows for early recovery of R&D costs in Japan. It is thus succeeding in stimulating drug development activities, as exemplified by a recent increase in the number of new drug development projects and investment in Japan. On the other hand, reducing the prices of drugs that have exceeded initial sales predictions contradicts the supposed commitment to promote innovation, and makes active investments less predictable for business.

Recommendations:

- The Government of Japan should make the new drug pricing system permanent so that innovation is rewarded. The new system helps stimulate more continuous investment in drug development in Japan, which is much needed if the Japanese pharmaceutical industry is to survive in the face of fierce global competition. At the same time, the system is expected to promote development of innovative new drugs worldwide, as well as the development of as-yet unapproved drugs and drugs for currently unapproved off-label use.
- The policy of reducing the prices of drugs that exceed initial sales predictions hinders innovation and increases uncertainty for business, and should be eliminated.

■ Access to new drugs

Yearly status report: no progress. A blanket maximum prescription length of 14 days is imposed on new drugs in the first year after their launch onto the market. Patients on such drugs are, therefore, required to visit the hospital every two weeks to re-fill their prescription. Until this restriction is lifted, medical institutions will continue where possible to avoid adopting and prescribing new drugs, thereby delaying patient access to the latest drugs and drug therapies. This approach is unnecessarily cautious: once new drugs are on the market in Japan, their safety is upheld by the post-marketing surveillance system, which is one of the most advanced systems in the world.

Recommendation:

- The prescription of new drugs is limited to 14 days in accordance with the stipulations of the Rules for Professionals in Charge of Healthcare Services under Health Insurance Programs (*Ryotan-kisoku*). These stipulations are unique to Japan and should be reviewed to improve patient access to new drugs.

■ Clinical trial environment / MRA

Yearly status report: limited progress. Japanese Good Clinical Practice (GCP) in clinical trials used to differ in many aspects from global standards, but is steadily being internationally aligned, not least through the December 2012 revisions. However, there has been no progress in extending the scope of the existing Mutual Recognition Agreement (MRA) for EU and Japanese Good Manufacturing Practice (GMP), which covers only 13 of the 28 EU Member States. Furthermore, limiting the MRA to solid oral preparations leads to duplicate trials and inspections for other products, incurring additional costs for the industry and delaying market introductions.

Recommendation:

- The existing EU-Japan MRA for EU and Japanese Good Manufacturing Practice (GMP) should be extended to cover all 28 EU Member States and expanded to include non-solid preparations. This will eliminate the potential for a drug lag due to duplicate inspections and examinations, and reduce GMP costs.

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VACCINES

Introduction

Japan's vaccine market has changed rapidly over the last few years. Newly introduced vaccines include the inactivated poliovirus vaccine and the quadruple combination vaccine, DTaP-IPV (Diphtheria-Tetanus Toxoids-Acellular Pertussis-Adsorbed and Inactivated Poliovirus Vaccine), which came onto the market in 2012. A revised Immunization Law took effect in April 2013, making Hib (*Haemophilus influenza*), human papillomavirus and pneumococcal 7-valent vaccines part of Japan's Routine Immunisation (RI) system, with adverse reaction reporting becoming a legal requirement.

Improvements in the RI system indicate that Japan is catching up with the EU and US in numbers of approved antigen types. However, the threat of an outbreak of infectious disease still exists and protection by vaccines in Japan remains inadequate. Reports suggest that the rubella epidemic caused a temporary vaccine shortage and the H7N9 influenza outbreak in China had the potential to become a pandemic. Although a project was convened by the Ministry of Health, Labour and Welfare (MHLW) aimed at establishing facilities to commercially produce cell culture-based vaccines for influenza, products developed by the three participating domestic companies remain at the approval stage or are under review, leaving Japan vulnerable. Many paediatric combination vaccines needed to prevent infectious diseases in infants still have not been approved. In other countries, the tight immunisation schedule for infants has been alleviated through approval of a variety of such vaccines and these have been in use now for more than 10 years. Japan lags behind these countries in introducing and routinely administering paediatric combination vaccines. Japan approved the DTaP-IPV combination vaccine in 2012, 15 years behind Europe.

Prior to revision of the Immunization Law, the Immunization Committee under the Infectious Diseases Subcommittee of the Health Science Council was elevated to the Immunization/Vaccine Subcommittee, under which three more subcommittees were formed for basic immunisation policy; research, development and manufacturing/logistics; and adverse reactions. These should have served as the official forum for impartial discussion on the vaccines needed for the Japanese people, similar to ACIP (the Advisory Committee on Immunization Practices) in the US. However, in June 2013, despite the fact that discussions on cervical cancer vaccines in the Adverse Reactions Committee had not concluded, MHLW made an ambiguous decision to stop recommending routine vaccination for cervical cancer, while still allowing the practice to continue. This decision raised doubts within and outside Japan, similar to a decision in 2011 to temporarily suspend immunisations with Hib and pneumococcal vaccines. It was pointed out that Japan needs "an independent advisory committee such as the ACIP", rather than "a committee organised by government bureaucrats" (*Lancet*; 382: 768 (2013)). EFPIA and the EBC believe that Japan would benefit from improved awareness of vaccines among the public, media, regulators and policy makers.

Under the previous Government, a subcommittee for regulatory reform was established in the Government Revitalisation Unit (GRU) of the Cabinet Office. In July 2012, after discussion and due consideration, a cabinet decision approved the following four actions: (1) expansion of the scope of the EU-Japan MRA (Mutual Recognition Agreement) to encompass biological products including vaccines, (2) exemption of vaccines from redundant in-house testing in Japan, (3) periodic review of the MRBP (Minimum Requirements for Biological Products), and (4) routine vaccination with vaccines recommended by the World Health Organisation. Progress since then has been limited to slight revisions made in September 2013 to the MRBP for individual vaccines, and improvements in relation to routine vaccination, but there has been no movement on the other two actions. The new political administration that came into power in late 2012 established a "Regulatory Reform Council" directly under Prime Minister Abe, but whether or not it will continue to promote the previous agenda remains unclear.

EFPIA and the EBC request the Government to promote dialogue and implement the reform necessary to encourage Japanese and foreign vaccine manufacturers to invest in developing and producing vaccines (especially paediatric combination vaccines) that contribute to improving preventive medicine in Japan. We believe MHLW should continue to act on the cabinet decision of the GRU and work towards regulatory reform, revise the non-clinical and clinical guidelines for preventive vaccines against infectious diseases, establish adjuvant (immunological stimulator) guidelines, and implement vaccine policy based on scientific evidence that reflects the interests of vaccinees.

Abbott Japan	Guerbet Japan
Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Baxter	Lundbeck Japan
Bayer Yakuhin	Merck Serono
Bracco-Eisai	Nihon Servier
Chugai Pharmaceutical	Nippon Boehringer Ingelheim
CSL Behring	Novartis Pharma
Ferring Pharmaceuticals	Novo Nordisk Pharma
Galderma	Sanofi
GE Healthcare Japan	Shire Japan
GlaxoSmithKline	UCB Japan

Key Issues and Recommendations

■ Periodic review of MRBP (Minimum Requirements for Biological Products)

Yearly status report: some progress. The report on “Research on Change in the Pharmaceutical Environment and Positioning of MRBP” produced as part of the Research on Regulatory Science of Pharmaceuticals and Medical Devices Programme, underwent various revisions including major changes to the sections on test items and methods. It was released for public comment in February 2013 and issued officially in September 2013. Unfortunately, the report is unclear as regards predefined timing, procedures for revision, criteria for listing, and administrative process and there is no allowance for periodic revision (for example, the quality requirements for vaccines should be regularly revised to reflect state-of-the-art science and technology).

Recommendation:

- In order to harmonise with other regions, the current MRBP should be abolished, and its contents consolidated and integrated into the Japanese Pharmacopoeia.

■ Elimination of redundant quality testing for imported vaccines

Yearly status report: no progress. Vaccines that have already undergone quality testing in the EU are subject to mandatory retesting after import as a condition for release in Japan. National testing is conducted based on the MRBP. A Summary Lot Protocol (SLP) was introduced in 2012 to ensure rigorous control of vaccine quality. Thus from a scientific point of view, testing all items after import and national testing should not be necessary.

Recommendation:

- The Government should provide a scientific and technical rationale to justify mandatory retesting and omit retesting where no rationale can be demonstrated.

■ Expansion of target countries and scope of items in EU-Japan Mutual Recognition Agreement (MRA)

Yearly status report: no progress. The top priority for the EU-Japan MRA should be its expansion to include the remaining EU Member States currently not covered by the agreement, but at present this does not appear to be under discussion. The MRA should also be expanded to include biopharmaceuticals and vaccines to shorten import times, enabling vaccines to reach people more promptly and contribute to preventive medicine.

Recommendations:

- Expand the MRA to include all EU Member States.
- Expand the MRA to include biopharmaceuticals and vaccines.

■ Incorporate WHO-recommended vaccines into routine immunisation

Yearly status report: progress. The revised Immunization Law took effect from April 2013 with three vaccines (Hib, human papillomavirus, pediatric pneumococcal) newly included in the RI. A decision on including the remaining four WHO-recommended vaccines (varicella, mumps, adult pneumococcal and hepatitis B) in the RI will be taken this fiscal year, and on rotavirus vaccine as soon as possible. An Immunization Vaccine Subcommittee of the Health Science Council has been set up, and discussions are ongoing.

Recommendation:

- The remaining four WHO-recommended vaccines and rotavirus vaccines should be added to the RI. Ultimately, all vaccines should be included in the RI.

■ Revise/Establish development guidelines

Yearly status report: no progress. In 2010, guidelines on clinical trials for preventive vaccines against infectious diseases came into effect, but provided no clear explanation of why dose-response studies using Japanese subjects are required. The argument that the dosage regimen used worldwide needs to be amended for Japanese people is not convincing. Guidelines are needed for adjuvants, which will be increasingly important in future.

Recommendation:

- The non-clinical and clinical guidelines for preventive vaccines against infectious diseases should be revised, and adjuvant guidelines should be established.

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COSMETICS & QUASI-DRUGS

Introduction

European companies produce a wide variety of innovative and safe cosmetic and quasi-drug products that consumers value and enjoy. The products improve their daily lives in many ways, helping them to keep their bodies clean and healthy, protecting them against the damaging effects of extreme weather, preventing dental cavities and the spread of harmful microorganisms, and improving the way they look. EU cosmetics companies work to ensure the quality, efficacy, safety and environmental sustainability of cosmetics by investing in the research and development of new ingredients and technology, conducting clinical studies on efficacy and safety, monitoring global developments in scientific knowledge, providing information to consumers and meeting or exceeding strict post-marketing surveillance and control requirements in accordance with Good Vigilance Practice (GVP) and Good Quality Practice (GQP).

Japan is the second largest market for cosmetics in the world with sales of 1,810 billion yen in 2011. Japan imported cosmetics valued at about 190 billion yen in 2012, of which cosmetics from the EU accounted for 75 billion yen. European cosmetic and quasi-drug products comprise a large share of imports because Japanese consumers recognise their value. However, European companies face challenges in bringing cosmetic and quasi-drug products to them in an efficient manner due to Japan's lack of regulatory transparency, the low degree of harmonisation between its product standards and those used in other parts of the world, and its unnecessarily complex approval and manufacturing requirements. As a result, the launch of many European cosmetic products in Japan is severely delayed, despite the fact that the same products are already in global use and have clinically proven efficacy. Some quasi-drugs even need to be reformulated because their global version uses new active or inactive ingredients for which approval is too time-consuming or difficult to obtain in Japan.

For example, information is very limited in Japan on which active and inactive ingredients have already been approved. The EU and Japan maintain different rules governing which ingredients are allowed in cosmetics, expressed respectively in terms of negative and positive lists. Even if an ingredient does not require regulatory approval in Japan when used in a cosmetic, the use of the same active ingredient in a quasi-drug often requires a lengthy approval process. Moreover, approval of products meeting existing approval standards is delegated to the prefectural authorities, but different prefectural offices often have inconsistent interpretations of how the approval standards should be met.

Globalisation has brought unprecedented benefits to consumers world-wide, in terms of new product benefits, greater variety, higher quality and lower prices. However, in any country where the product approval process deviates from international standards and practices, there is an inevitable and significant increase in the complexity of that process and its associated cost. Increasing transparency, streamlining the approval process, and promoting greater regulatory harmonisation between Japan and the EU would make it easier to bring more high-value-added products to Japanese consumers in a timely manner.

The EBC believes that the EU and Japan should lead the way by bilaterally negotiating harmonised regulations for quasi-drugs, expanding efficacy claims, and aligning their respective positive and negative lists. The EU-Japan FTA/EPA should be an important vehicle for this process. The EBC also strongly supports greater leadership by the EU and Japan in the International Cooperation on Cosmetic Regulation (ICCR), an international group of cosmetic regulatory authorities from the United States, Japan, the EU and Canada that meets to discuss how to promote multilateral regulatory coordination and harmonisation in order to minimise barriers to trade, while maintaining the highest level of global consumer protection.

Key Issues and Recommendations

■ Reform of the quasi-drug approval system

Yearly status report: no progress. The Ministry of Health, Labour and Welfare (MHLW) cooperated with industry in disclosing a list of approved ingredients for medicated cosmetic-type quasi-drugs in December 2008. However, regulatory transparency remains insufficient and product reviews are slow.

Recommendations:

- Review times for quasi-drugs should be reduced: The EBC recommends a streamlined and expedited product approval and partial change process, especially for products using active ingredients that have been previously approved for use in similar products. This would allow reviewers to spend more time on products that present a higher risk.
- Quasi-drug transparency should be increased: Japan should establish a clear process and schedule for regularly updating and expanding the list of approved active and inactive ingredients.

■ Expansion of efficacy claims for cosmetics and quasi-drugs

Yearly status report: some progress. A scheme for specifying the efficacy of cosmetics was presented in the “Notification on Enforcement of Pharmaceutical Affairs Law” of 1961. Subsequently, 55 efficacy claims were defined for cosmetics in the “Notification on Revision of the Scope of Efficacy Claims for Cosmetics” of 2000. In 2011, the efficacy claim of “making fine wrinkles due to dryness less noticeable” was added to the list after many years of advocacy from the Japan Cosmetic Industry Association (JCIA), supported by the earlier establishment and publication of the “Guidelines for the Method for Evaluating the Functions of Cosmetic Products” by the Japanese Cosmetic Science Society. This development marks significant progress for the cosmetics industry as it is the first step in harmonising Japanese efficacy claims for cosmetics with those of other countries. The EBC hopes that, at the level of quasi-drugs, an application expanding the efficacy claim of “fine wrinkles” to “wrinkles” will be approved. The scope of efficacy claims approved in Japan is still narrower than in other countries, which hinders the entry of foreign-made cosmetics to the Japanese market. Further expansion of the scope of efficacy claims is required to reflect advancing research and technology and accommodate consumer demand for cosmetics and quasi-drugs.

Recommendation:

- The scope of positive efficacy claims for cosmetics and quasi-drugs should be expanded to harmonise the range of efficacy claims in Japan with those of foreign countries. In particular, the EBC requests that the claim of “preventing photo-ageing caused by exposure to ultra violet light,” which is proposed by the JCIA, be approved.

■ Elimination of non-tariff barriers for cosmetic and quasi-drug imports

Yearly status report: no progress. Every time a company imports a particular cosmetic product, it is required, under the Pharmaceutical Affairs Law, to re-submit the original import notification documentation, obtained when the product was first approved or its product notification submitted. This requirement is wholly unnecessary yet time-consuming to fulfil. Now the MHLW has announced that importers of cosmetics and quasi-drugs will also need to re-submit these documents whenever they renew their business licence. Moreover, because previous versions of a quasi-drug cannot go through the quality check process after a partial change request has been approved, and given the difficulty in predicting approval timing, sea freight importers must hold large amounts of excess stock in Japan to ensure a stable supply. This results in unnecessary costs. In April 2013, the MHLW announced changes in the monitoring of and the guidelines for importing drugs and poisons, but this did not extend any benefits to cosmetics importers, apart from imports for personal use.

Recommendations:

- The requirement for resubmission of import notification documentation should be eliminated in order to reduce unnecessary paperwork and the time required to import products.
- After partial change approvals, there should be a grace period during which the previous version of imported products can undergo quality checks and still be sold.

■ Increased transparency for cosmetic ingredients

Yearly status report: no progress. The MHLW has issued notices to increase transparency regarding which medical ingredients fall into the product category prohibited for use in cosmetics. However, the inconsistency between Japan and the EU in maintenance of positive and negative lists remains unaddressed.

Recommendation:

- The EU and Japan should work towards harmonisation of regulations on ingredients.

■ Application of the same legal standards to parallel importers

Yearly status report: no progress. While the administrative authorities have charged some illegal traders with the import and sale of cosmetics without authorisation, or the distribution of products that do not carry the legally required labelling, illegal products are still distributed and marketed by parallel importers on internet marketing sites beyond the reach of administrative supervision and enforcement. There are cases of the import and sale of products without legal labels, products deviating from Japanese regulations, and counterfeit products. These products do not comply with the requirements in place to protect consumers and they also impair fair competition, to the detriment of law-abiding manufacturers and authorised importers.

Recommendation:

- The Japanese Authorities should conduct more effective surveillance and better enforce existing laws related to the import and sale of cosmetic products.

■ Establishing of alternatives to animal testing

Yearly status report: some progress. Use of alternatives to animal testing was officially recommended in the February 2011 MHLW Administrative Circular. Apart from the issued guidance mentioned above, the MHLW also issued guidance on replacing the skin sensitisation test to take effect from May 2013. This guidance corresponds to OECD 442A and OECD 442B. Seven years have passed since the MHLW issued its “Administrative Circular on Alternatives” in July 2006, indicating that test reports based on the OECD (Organisation for Economic Co-operation and Development) alternatives or their equivalent might be used in applications for approval of quasi-drugs. Issuance of further guidance is expected for other alternatives. The Japanese regulatory authorities have already agreed to continue to cooperate and coordinate with and support the activities of the International Cooperation on Alternative Test Methods (ICATM) in the International Cooperation on Cosmetic Regulation (ICCR).

Recommendations:

- The Japanese authorities should issue similar guidance for, and promote the use of, other alternatives that have already been adopted by the OECD and other organisations and for which The Japanese Centre for the Validation of Alternative Methods (JaCVAM) has completed an evaluation and sent a proposal for adoption to the Government.
- Japan should establish an animal protection environment based on the 3R (reduce, reuse, recycle) principle, and abide by its international commitment to protection of humans and the environment.

Consumer Goods

Liquor
Food & agriculture

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LIQUOR

Introduction

Europe is the leading exporter of liquor and wine worldwide. The Japanese liquor market is one of the largest in the world with estimated annual sales of 6 trillion yen and growing wine consumption. Despite such figures, in terms of value, foreign imports in 2012, at 212 billion yen (according to Japan Customs), accounted for a mere 6% of the total Japanese liquor market, including beer and beer-like products. The main reasons for this are clear. While the Government of Japan has implemented a notable reduction in taxes on liquor, the country still lags behind the rest of the world in applying international standards for product definition and in eliminating non-tariff barriers to market access.

In compliance with World Trade Organisation (WTO) rulings, the Government of Japan reduced the gap in liquor tax rates between domestically produced distilled liquor (*shochu*) and imported liquors. By 2002, Japan had eliminated tariffs on whisky, brandy, vodka, rum, liqueurs and gin. Despite this, Japan still does not comply with all relevant WTO rulings and international standards. The Ministry of Finance (MOF) has made clear its long-term goal of classifying wine and Japanese *sake* in the same category, ignoring fundamental differences between the two products. The EBC is concerned that this would be in contravention of the 1998 WTO ruling, which prescribes that the overriding determinant when setting tax categories for alcoholic beverages should be the level of substitutability in terms of production and consumption. In contrast to Japan, the EU, US and Australia have all implemented the WTO ruling so that spirits, beer, wines and intermediate products are placed in separate general categories, complemented by specific categories for country-typical products.

Japan continues to impose tariffs on both sparkling wine (182 yen/litre) and still wine (125 yen/litre), which are around five and three times higher, respectively, than the levels imposed in the EU. The EBC cannot understand the grounds for such high tariffs nor why there is a difference between the tariffs imposed on sparkling and still wine. Japan has almost no production of sparkling wine, yet it carries a higher tariff than still wine.

Japan's tax system for beer is equally baffling. Instead of taxing beer based on alcohol content or as a heterogeneous liquor group, beer in Japan is taxed on malt content, divided into basically three categories, with "real beer", which has a malt content of more than 67%, attracting the highest rate. All European beer, apart from a few exceptions, is classified as real beer. The tax system thus has the unfortunate effect of making arguably lower quality beer cheaper and so more accessible. As a result, low malt beer, or *happoshu*, and 0% malt-based beer make up almost 40% of the Japanese beer market. The EBC believes that the tax system should be made independent of malt content so that high quality beer is not taxed more heavily than low malt or 0% malt based beer.

In Japan, the use of lot codes (traceability information) is not compulsory under the Food Sanitation Law, although it is recommended in the Ministry of Health, Labour and Welfare (MHLW) administrative guidelines. By contrast, the EU makes it obligatory to display lot codes on food and beverage products, as such codes fulfil an important role in any effective and efficient product recall or withdrawal process. Whilst most importers of EU liquor products ensure that lot codes are in good order when the products are marketed and put into distribution in Japan, it is common practice for opportunistic traders, prioritising business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up. The EBC urges the Japanese Government to take more proactive measures to protect the health and safety of Japanese consumers by: 1) forbidding the sale of liquor with lot codes that have been erased, tampered with or covered up, and 2) introducing penalties for the wholesale or retail of liquor bottles whose lot codes have been erased, tampered with or covered up. The EBC cannot understand why Japan permits the sale of products with erased lot codes as the vast majority (30 out of 34) OECD member countries do not.

Finally, the lack of accurate Geographical Indicator (GI) definitions in Japan's Liquor Tax Law is of great concern to the EBC. In the long term, this lack may hinder the ability of European businesses to compete in the Japanese market. The EBC therefore calls on the EU and Japan to adopt common definitions within the context of the EU-Japan FTA/EPA.

Key Issues and Recommendations

■ Traceability

Yearly status report: no progress. Lot codes (traceability information) fulfil an important role in any effective and efficient product recall or withdrawal process. In the case of a serious health threat, delays to such processes could endanger consumers: a rapid, targeted and efficient response is vital in order to protect them and preserve their confidence in the supply chain. Whilst most importers of EU liquor products ensure that lot codes are in good order when products are marketed and put into distribution in Japan, it is common practice for opportunistic traders, prioritising business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up.

Recommendation:

- The Government of Japan should issue legislation, reinforced by penalties, that forbids the wholesale or retail of liquor bottles whose lot codes have been erased, tampered with or covered up.

■ Tariff on wine and white spirits

Yearly status report: no progress. Japanese wine duty is arbitrarily high in comparison with the duty applied to beer, brandy and whisky, which was reduced to zero in 2002 (in accordance with agreements reached at the 1998 WTO panel). The temporary zero tariff on white spirits, rum, gin, vodka and liqueurs should be made permanent.

Recommendations:

- The EBC urges Japan to completely remove all tariffs on wine.
- The EBC urges Japan to change the applicable tariff lines for white spirits to become permanently zero.

■ Liquor tax on beer

Yearly status report: new issue. The liquor tax on beer in Japan is based on malt content. This unfortunately puts real beer with a malt content of over 67% at a disadvantage and has created a situation where arguably lower quality beer is more favourably priced. This is very clear when looking at the market share of low malt beer, or *happoshu*, and 0%-malt based beer, which together account for almost 40% of the Japanese beer market.

Recommendation:

- Japan should revise its liquor tax system for beer to make it independent of malt content.

■ Additives

Yearly status report: no progress. The list of additives approved by the Japanese authorities for inclusion in liquor is outdated and differs greatly from the lists of other industrialised countries. In addition, the process for having additives declared safe is both very costly and time-consuming.

Recommendation:

- Japan should swiftly approve additives that are in common use among other industrialised countries.

■ Wine definition

Yearly status report: no progress. The Japanese definition of wine is too broad. The loose wine definition opens the door for different products to be sold as “wine”, misleading Japanese consumers and creating unfair competition for European wines, which meet the internationally accepted definition.

Recommendation:

- Wine definitions in Japan should conform to international specifications as defined in the EU and the US and endorsed by the International Federation of Wines and Spirits.

■ Geographical Indicators

Yearly status report: no progress. GI terminology in Japan is not compatible with the EU-origin concept and rules and threatens to undermine European products in the Japanese market.

Recommendation:

- The Government of Japan should reconsider the GI rules in its Liquor Tax Law and introduce amendments in line with widely accepted EU definitions.

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FOOD & AGRICULTURE

Introduction

Generally speaking, Japan's regulatory environment favours the import of raw materials for use by the domestic processing industry, but hampers the import of packaged food, whether processed or not. The relative scarcity of imported packaged food in Japanese supermarkets compared to other developed countries bears witness to this. It can indeed be found in regular supermarkets, but the assortment is, with few exceptions, limited to only a fraction of the potential. The situation is better in upscale and gourmet specialist shops, where price matters less. However, there is no reason why imported European food should be either so expensive or exclusively upscale.

There are two main factors behind the current situation. The first and most important is tariffs. Food is purchased everyday and therefore price is a key decision factor for consumers when choosing what to buy. European packaged food is at a clear disadvantage as it is subject to tariffs that can represent a large proportion of the price, and in some cases the tariff is effectively even more than 100%. Ordinary butter is an example of this anomaly.

The second factor is the large number of non-tariff barriers that have a serious impact on the amount of food imported from Europe, in terms of both volume and variety. For example, Japan remains "out of sync" with other countries as the majority of food additives declared safe by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) are still not approved in Japan, while many approved additives in Japan are not accepted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Japan has given only limited acceptance to scientific evaluations by international bodies, such as JECFA and the Codex Alimentarius Commission (CODEX), resulting in approval procedures in Japan that are both unnecessarily time-consuming and overly costly. The issues surrounding food enzymes are more or less the same as for food additives.

Another example of a non-tariff barrier to trade is that Japan does not recognise the EU's regulatory approach to *Listeria monocytogenes*. The EU approach distinguishes between foods that support the growth of *Listeria monocytogenes* and foods that do not. The EBC believes that food products recognised by the EU as not supporting the growth of *Listeria* and containing only a non-harmful level of *Listeria* should be approved for import.

Last but not least, despite Japan's recent recognition of organic certifications issued by the new EU Member States, and the EU's recognition of organic certifications issued by Japan, the Organic-JAS (Japan Agricultural Standard) Mark still cannot be used for many EU certified organic products. Moreover, Japan lacks comprehensive legislation for several categories of agricultural products (such as honey). Due to the complexity of obtaining the Organic-JAS Mark and the limitations in product scope, organic food in Japan lags far behind that in other developed markets in terms of market share.

The EBC is very keen to work closely with all related parties in the Government of Japan and the European Commission to help bring about effective and positive change to support the goal of providing consumers in Japan with a much wider variety of safe, high-quality food. European food products in subsectors that are not hampered by high tariffs or non-tariff barriers are very popular in Japan, clearly indicating the demand for European food. We believe that our closely shared principles strongly support the potential for success of the EU-Japan FTA/EPA. Under the agreement, tariffs should be abolished, standards harmonised and market authorisations of both regions mutually recognised. The EBC Food Committee believes this can be achieved without compromising food safety. Such an agreement will lead to more choice in supermarkets, stimulating healthy competition in the food and agricultural sectors of both zones, and to European food becoming more accessible, something we know Japanese consumers would appreciate.

Beltrade	Nichifutsu Boeki
Bresse Bleu Japon	Norwegian Seafood Export Council
CSM Japan	Perfetti Van Melle Export Far East Japan
Danisco Japan	Pick
Danone Japan	PinguinLutosa Japan
DSM Nutrition Japan	Puratos Japan
Hiestand Japan	Roquette Japan
IKEA Japan	SKW East Asia
Japan Europe Trading	TÜV Rheinland Japan
Mie Project	Unilever
Nestle Japan	Valrhona Japon

Key Issues and Recommendations

■ Tariffs & quotas

Yearly status report: no progress. Japan continues to impose high import duty rates on many foods and food ingredients. Severe inflation in the cost of ingredients and transport, coupled with high import duties, make some imported foods prohibitively expensive. Examples include butter (with an import duty rate of 35% plus 1,159 yen/kg), cheese (26-40%), chocolate for professional use (29.8%), confectionery (25%), syrup (24% plus sugar tax related to quota), fruit juice and fruit puree for babies (21.3%), and herbal tea (15%). Quotas also exist, for example for dairy products and sugar, and add a further tax to be paid when importing food containing such ingredients.

Recommendations:

- The Government of Japan and the EU should abolish tariffs on food products as part of the EU-Japan FTA/EPA.
- The quota system should be abolished, especially for dairy products and sugar and its derivatives.

■ Food additives

Yearly status report: slow progress. Differences in approved additives are still common between Japan and other major markets. In 2002, Japan started an exercise to remedy this situation, planning the approval of 46 additives (now 45), but ten years later this exercise is still not finalised. In the meantime, further new additives have been entering foreign markets, extending the differences between Japan and elsewhere. A further concern is the approval process in Japan itself. Currently the process is both time- and money-consuming as well as being highly non-transparent and lacking any deadlines. Both foreign and domestic companies would benefit from a system where each step has clear deadlines to be followed by the authorities.

Recommendations:

- The Ministry of Health, Labour and Welfare (MHLW), in cooperation with the Food Safety Commission (FSC), should swiftly approve the remaining 11 additives in the original list of 45 items.
- Lecithin of sunflower origin should be approved without further delay.
- MHLW together with the FSC should introduce deadlines for each part of the approval process. Furthermore, repeated requests for additional information should be avoided.
- MHLW and the FSC should ensure that standards of use in Japan are not in conflict with international standards of use. Current examples are sulphur dioxide and sorbic acid (potassium sorbate).

■ Food enzymes

Yearly status report: new issue. Many food enzymes widely used in the EU and USA are not approved in Japan. Furthermore, Japan lacks a dedicated approval system for food enzymes. This limits the development of food with a reduced content of food additives. Moreover, the limited number of approved enzymes is a restricting factor in the development of the Japanese food business for the benefit of consumers. In Japan, food enzymes are approved using a procedure based on the standards for safety assessment of food additives produced using genetically modified microorganisms, a procedure that is both time-consuming and non-transparent. Furthermore, while MHLW is the contact point for applications for approval, the deciding body is the FSC. The FSC is largely independent from MHLW and usually comprises academics, doctors and miscellaneous experts, making it difficult for an applicant enquire about exactly what materials they will need for a particular application.

Recommendations:

- The EU-Japan FTA/EPA should guarantee that food enzymes in wide use in the EU and accepted as safe by JECFA will be approved for immediate use in Japan.
- MHLW should establish a dedicated approval system for food enzymes.

■ Beef and processed food including beef and by-products (casings, gelatines)

Yearly status report: progress. In 2013, France and The Netherlands were granted approval to export beef to Japan. Several other EU Member States have started the approval process, but progress is very slow.

Recommendations:

- The FSC should speed up the approval process for EU Member States that have already submitted data to the Ministry of Agriculture, Forestry and Fisheries (MAFF) and MHLW.
- Processed food containing beef, bovine gelatines, or products made with beef casings, should also be approved for import as they are widely used in the European food industry, which has already established high safety standards.

■ Listeria Monocytogenes

Yearly status report: no progress. Listeria monocytogenes is a widespread pathogenic bacterium. If allowed to grow, it can contaminate food causing a mild illness, called listerial gastroenteritis, or in certain cases, a potentially lethal disease called invasive listeriosis. The EU standard, fully taking into account consumer safety, stipulates zero tolerance for food that supports growth of the bacteria, whilst accepting minute levels of L. monocytogenes (less than or equal to 100 cfu/g) in food not supporting growth of the bacteria. However, Japan makes no such distinction and bans all foods that contain L. monocytogenes

Recommendation:

- Japan should review its position on L. monocytogenes and consider aligning regulations with the “double approach” adopted by the EU, Canada and other countries, and also supported by the principles of CODEX and the FDA.

■ Yearly analysis (additives, bacteriological) at Customs

Yearly status report: new issue. At present, certain foods and all drinks imported into Japan require analysis on an annual basis. As food safety standards in the European Union are as high as in Japan, there should be no need for Customs to conduct additional analyses of EU food imports. Such analyses cost time and money and do not help in improving consumer safety, especially since they are carried out on a random basis. This is an area of great concern to food importers as it results in unnecessary costs and delays which can lead to wasteful disposals. In cases where testing of imported foods at Customs is justified, such as products that are new to the market, the EBC recommends that a swift appeal system be established before disposal of a product that is declared unsafe.

Recommendations:

- Japan should eliminate the need for a yearly analysis at Customs of EU foods (additives, bacteriological).
- Japan should introduce a swift appeal system whereby independent official analyses that indicate a product is safe can be used as justification for a retest.

■ Organic food – Full equivalence between EU and Japan

Yearly status report: slow progress. The market for organic food is still very small in Japan, estimated at a mere 0.4% of the total food market. Part of the reason for this is the regulatory environment where the scope of Organic-JAS still does not include meat or animal-based products or honey, although this is covered by organic labelling both in the EU and the US. This means that, for instance, chocolate with a content of more than 5% of honey or milk cannot be labelled Organic-JAS. Furthermore, although supplementary certificates from EU embassies are no longer needed, the requirement that an individual organic certificate needs to accompany every shipment is an administrative burden for both importers and exporters.

Recommendations:

- Additives that are allowed in organic food in the EU should also be allowed in organic food in Japan.
- MAFF should declare full equivalence between Organic-JAS and Organic-EU.
- Japan should expand the scope of Organic-JAS to include meat, animal-based products and honey.
- Japan should abolish the need for individual organic certificates for every shipment. An annual certificate should suffice.

Industry

Automobiles

Automotive components

Aeronautics

Space

Defence & security

Construction

Materials

Energy

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AUTOMOBILES

Introduction

“Abenomics” is a mixed blessing for European automobile importers. Increasing consumer confidence and the wealth effect of higher stock prices have boosted sales of European cars in a declining passenger car market. In the first eight months of 2013, sales by EBC Automobile Committee members rose by 14 percent to 162,000 units, while the market as a whole declined by 8 percent. The depreciation of the yen resulting from the Bank of Japan’s ultra-loose monetary policy has however worsened the terms of trade for European automobile importers. In euro terms, the increased revenue from higher sales is barely sufficient to offset the impact of the adverse movement in the euro-yen exchange rate. The Abe Government’s pledge to revitalize the Japanese economy by structural reform and deregulation does not yet extend to the automobile industry. The non-tariff barriers to European imports many of which were identified in the Scoping Exercise, which preceded the launch of the FTA negotiations, continue to add to the cost of doing business in Japan for European importers of both passenger cars and commercial vehicles.

As noted in last year’s Annual Report, the potential passenger car market in Japan open to competition from imports is restricted by the inexorable growth of the *kei* car segment. “*Kei*” or mini-cars are a vehicle classification unique to Japan: such vehicles are restricted to a maximum length of 3.4 m, a width of 1.48 m, a height of 2 m and an engine displacement of 660 cc and below. *Kei* cars benefit from lower automobile related taxes, automobile liability insurance and motorway tolls and are subject to less stringent overnight parking requirements. No foreign model qualifies for *kei* car designation, an artificial construct of the Japanese regulatory system. In 2012, *kei* cars accounted for 34% of the domestic passenger car market, while in the first eight months of 2013 that share had risen to 37.5%.

Fortunately, there appears to be growing public recognition that it is anomalous for *kei* cars to be subject to a much lower level of taxation than subcompact cars with a comparable performance and pre-tax purchase price. The Government of Japan’s (GOJ) plans to raise consumption tax in stages from FY 2014 provides an opening to abolish the Automobile Acquisition Tax, which is levied at a lower rate on *kei* cars, and equalize the level of automobile and *kei* car tax. The EBC Automobile Committee urges the GOJ to seize this opportunity and to give European importers of subcompact cars the chance to compete in the Japanese market on a level footing with *kei* cars.

The harmonisation of technical standards and certification procedures between the EU and Japan remains a top priority for European passenger car and commercial vehicle importers. The EBC Automobile Committee looks to the FTA negotiations to realise this objective.

The European Commission has undertaken to review 12 months after the start of the FTA negotiations, Japan’s implementation of its commitment given in the Scoping Exercise to eliminate NTBs, in particular in the automotive sector. If that implementation is not fully satisfactory, the Commission may suspend the negotiations. The EBC Automobile Committee regrets that at the half-way mark, Japan has so far made only limited progress. If the GOJ wishes the negotiations to continue, and eventually to reach a mutually satisfactory conclusion, the EBC Automobile Committee hopes that Japan will show greater willingness in the negotiations to meet the EU’s expectations, in particular with regard to:

- 1) the adoption of the relevant UN regulations in all areas where Japan requires certification for M1 vehicles but does not currently accept a UN approval as demonstrating compliance with Japan’s national requirements, so that a vehicle certificated in the EU can be sold in Japan without modification or further testing, and
- 2) the adjustment of the fiscal and regulatory privileges enjoyed by *kei* cars (as explained above).

Key Issues and Recommendations

■ Harmonisation of technical standards and certification procedures

Yearly status report: limited progress. The EBC Automobile Committee welcomes Japan's proposals in the UNECE for the adoption by 2016 of an International Whole Vehicle Type Approval (IWVTA) system and calls for its earlier implementation on a bilateral basis. This would make mutual recognition of vehicle certification possible between Japan and the EU.

Recommendations:

The Government of Japan should:

- Accelerate the adoption of existing UN Regulations in areas where Japan retains unique national requirements.
- Work closely with EU Member States and the European Commission to implement on a bilateral basis the proposal for an International Whole Vehicle Type Approval system.

■ Tax reform

Yearly status report: little progress. Compared with other countries, Japan imposes an excessively heavy tax on the purchase and ownership of motor vehicles.

Recommendations:

The Government of Japan should:

- Abolish the Automobile Acquisition Tax and Tonnage Tax.
- Take advantage of the revision of the consumption tax to simplify the structure of the taxation of automobiles and to reduce the overall tax burden on motorists in line with international best practice.
- Conduct a comprehensive review of the taxation on fuels from the perspective of environmental policy.
- Adopt and implement, as early as possible, internationally harmonised standards for measuring fuel efficiency and exhaust emissions to assess environmentally friendly vehicles.

■ Kei cars

Yearly status report: no progress. The continued existence of regulatory and fiscal privileges for *kei* cars distorts competition.

Recommendation:

- The Government of Japan should put *kei* cars and other motor vehicles on the same regulatory and fiscal footing.

■ High Pressure Gas Safety Act

Yearly status report: little progress. The High Pressure Gas Safety Act acts as an impediment to the introduction into the Japanese market of new environmental and safety technologies such as fuel cell, LPG and CNG vehicles, hydrogen airbags and refrigerants with a low global-warming potential for car air-conditioning units, which are already in use in the EU and elsewhere.

Recommendation:

- The Government of Japan should take the necessary steps to allow the use of these technologies with the minimum administrative burden.

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AUTOMOTIVE COMPONENTS

Introduction

Mentioning the Tohoku disaster is unavoidable when dealing with the automotive components sector. While the sector shared in the human tragedy, it also became apparent that its supply chain was very vulnerable. Several Japanese companies had depended on a single supplier based in the affected region and this severely hurt production upstream. This, together with the strong yen, has changed the business environment: Japanese vehicle manufacturers are today more open to doing business with foreign companies, both from a monetary perspective and to spread their risk via a second supplier.

At the same time, the process of globalisation and intense competitive pressures have together caused the outsourcing of automobile component development and supply to emerge as a clear trend in the European automobile industry. The European system now offers low risks, reasonable prices and flexibility. In the past, European component manufacturers that had enjoyed success with Japanese transplants in Europe had seldom been able to build on this base to become suppliers of the parent company in Japan. However, European firms are finding that, as a result of recent changes in the Japanese automobile manufacturing sector, new opportunities are surfacing and an increasing number of companies are now dedicating resources to attracting business in Japan, investing in local infrastructure and improving technical competence, with the goal of promoting more direct contact and closer relationships with Japanese clients. Against this background, the EBC greatly values the ongoing, regular dialogue between European component manufacturers and Japanese carmakers as a vital mechanism for sharing information and promoting understanding. It is hoped that this will, over time, foster increased opportunities for mutually beneficial business development.

As it stands, however, many Japanese firms are still uneasy about divulging proprietary information to outsiders, and continue to favour traditional suppliers for product design and production. It is standard business practice for Japanese automobile manufacturers to request an exact product instead of setting up a framework of open standards to fulfil, which reflects their lack of transparency and reluctance to consider new inputs, thus defying the global trend towards single platform development and volume production. The EBC feels that Japan's failure to use international technology makes its industry overly inward-looking, a situation unfortunately reinforced by the lack of English use. Japan still has some way to go to become a truly global market.

Japan is a member of Working Party 29 on transport issues within the United Nations Economic Commission for Europe (UNECE) and has recognised regulations related to tyres: Regulation no. 30 (Passenger Car), 54 (Light Truck, Truck & Bus) and 75 (Motorcycle). There have, however, been a number of slight discrepancies between Japan's regulations and those of UNECE, one of which being Japan's regulation corresponding to UNECE Regulation No. 54, which was stricter in the scope of its application. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) resolved this issue by widening the *Jishin* 1533 (2013) scope of new vehicle tyre approval to include not only tyres that conform to the Japan Automobile Tire Manufacturers Association's (JATMA) Year Book, but to Regulation No. 54 standards as well. The EBC greatly welcomed this action. It is vital that Japan continues to address such discrepancies and supports further regulatory harmonisation at the global level.

Finally, the EBC notes the almost oligopolistic situation in the Japanese tyre market, in particular for commercial vehicles. Brand-exclusive networks make it very difficult for outsiders to penetrate the market, leading to less competition, higher prices and less consumer choice.

Key Issues and Recommendations

■ Globalisation of the automobile industry

Yearly status report: progress. The EBC welcomes the opportunity that globalisation presents for innovative European firms to strengthen their relationship with Japanese automobile manufacturers in developing new products and sharing technical expertise. Japanese automobile manufacturers are increasingly making use of foreign tie-ups to develop their business and respond to competitive pressures both at home and abroad. Nevertheless, European automotive component and system manufacturers continue to face numerous challenges in promoting European technical expertise to automobile manufacturers in Japan. In this respect the traditional Japanese practice of working with affiliated companies presents obstacles and leads to the distortion of competition. Free and open competition would lead to more innovative and better quality products, something that would benefit Japanese manufacturers and consumers. Japan-specific requirements are common, and it is not unusual for specifications to differ between domestic and overseas production, even within the same company. It is, therefore, of crucial importance that Japan harmonises its regulatory framework to better accommodate the globalisation of the automotive components sector.

Recommendations:

- The EBC urges the Japanese automobile industry to focus more on the technical, commercial and logistics aspects of automobile production in the procurement of components and systems. Increased purchasing on a global basis and more emphasis on single platform development would improve the cost-effectiveness of the Japanese industry.
- The EBC recommends the application of free and open competition and the avoidance of excessive reliance on affiliated companies.
- Japan should recognise foreign test results to avoid the necessity of re-testing for the Japanese market.

■ Promoting information exchange

Yearly status report: limited progress. Face-to-face meetings between the European Association of Automotive Suppliers and Japanese car manufacturers were established in 1995 to promote information exchange between European and Japanese companies. These meetings have proven to be an extremely effective venue for discussing issues of mutual concern relating to products, platforms, global strategies and other important matters affecting the industry. The next meeting schedule is currently under negotiation between the European Association of Automotive Suppliers and the Japan Automobile Manufacturers Association. The EBC encourages top-level Japanese industry participation. The EBC also sees considerable potential value in the Japan Society of Automotive Engineers' (JSAE) Automotive Engineering Exhibition and the annual congress/paper presentation scheduled for 21-23 May, 2014 in Yokohama.

Recommendation:

- The EBC strongly supports the continuation of face-to-face meetings with leading representatives from the Japanese automobile industry. Such meetings have led to a greater understanding between European component manufacturers and Japanese car manufacturers. The EBC also hopes that the scope of these meetings will be expanded in future to include Japanese venues.

■ Tyres

Yearly status report: progress. The EBC appreciated the action taken by MLIT to improve market access in Japan for European tyres, especially with the issuance of *Jishin 1533* (2013). Despite this positive change and even though the Japanese authorities deem European tyres to be safe, some differences still exist between UNECE and Japanese regulations for tyres of commercial vehicles. This can, in some situations, lead to misunderstandings and uncertainties about what is really allowed.

Recommendation:

- The EBC urges Japan to further accelerate worldwide harmonisation of technical standards and regulations.

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AERONAUTICS

Introduction

Japan's cooperation strategy has been evolving recently. A preferred US partner since the post-war days, the country is now opening up to more balanced political and economic ties with other regions, among them, the EU. Even though it may take some years, the ongoing FTA/EPA and TPP negotiations are indicating a shift to more worldwide cooperation in the future.

Politics have long influenced the aeronautical industry in Japan, sometimes favouring the long-term relationship with the US over business realities. The Airbus A350 selection by Japan Airlines (JAL) is a sign that traditional Japanese corporations may now be thinking differently. The private sector is expected to make business decisions based on economic grounds rather than politics, creating opportunities for Europe and Japan to develop new commercial and industrial ties. The military sector also seems increasingly open to consider cooperation with European manufacturers. The EBC will actively support this evolution.

Historically dominated by US manufacturers since the beginning of the 1950s, the Japanese commercial aircraft and helicopter market is among the largest in the world. The EBC welcomes the decision by a Japanese major airline to choose European products. This is clear evidence that Europe can lead the way when it comes to high technology, quality, customer services, and cost-effectiveness.

More than 30 years have passed since the beginning of the cooperation between Kawasaki Heavy Industries (KHI) and Eurocopter on the BK117 helicopter co-development programme. Collaboration between KHI/Mitsubishi Heavy Industries (MHI)/IHI and Rolls-Royce on the Trent engines are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. The Ministry of Economy, Trade and Industry (METI) and the Directorate General for Civil Aviation of France (DGAC) signed a Memorandum of Cooperation in Civil Aeronautical Industry in June 2013 at the Le-Bourget Airport in France. This was a new step for further Japan-EU cooperation in the future. An EU-Japan Aeronautics Industry Workshop will be held in March 2014 to identify specific projects.

While an "all-Japan-team" policy may be easy to manage in the short term, the EBC believes that it is unfit for this new era of competition. Proactive collaboration with successful European companies would enable Japanese corporations to strengthen their positions in commercial aeronautics. By joining a wider range of projects, Japanese firms would be able to expand their international business opportunities and further develop their technological base. The EBC feels that there are considerable opportunities for large-scale joint development programmes between Japanese and European industries, especially in the field of transport aircraft, and urges Japan's Government and aerospace players to support such initiatives.

Key Issues and Recommendations

■ Promoting partnerships with the EU

Yearly status report: progress. The aeronautics market is becoming more and more global, and Europe has strong competitive advantages. For example, European companies have experience in the area of high-end technologies that are environmentally friendly. Procurement decisions should be made not only on a competitive basis, but also with future technological advantages in mind. European manufacturers of commercial aircraft, engines, components, and navigational equipment offer state-of-the-art technology at internationally competitive prices. However, even with the decision of JAL to use European products in the future, the European share in the Japanese market for commercial aircraft and related equipment is still considerably smaller than its average share worldwide.

EBC consistently requests Japan to modernise its air traffic management system. European companies are recognised worldwide as setting state-of-the-art standards, yet they face great difficulty in even being considered in the process for new equipment procurement in Japan. The EBC deplores this situation, which may be keeping Japan from benefiting from the latest advances in safety standards.

Recommendations:

- The EBC encourages Japanese firms to diversify their sources of supply and consider the advantages of European products in the aeronautics field for the benefit of their customers, the general public, and shareholders.
- The EBC also urges the Japanese authorities to facilitate greater use of equipment from foreign manufacturers who can help them address the need for improvements in air transport safety.

■ Promoting industrial cooperation

Yearly status report: limited progress. Cooperation in commercial aircraft development in Japan is still biased in favour of North America. However, METI has supported international co-development of aircraft with Europe. European companies also need METI to support similar cooperation as in the case of the Boeing 787 programme. The EBC is convinced that there are mutually beneficial opportunities for cooperation between European and Japanese firms. METI's support for the Trent 1000 engine, the agreement on supersonic technologies, and the development of Structural Health Monitoring (SHM) technologies should pave the way for more aeronautics cooperation. Furthermore, the scale of Japanese financial support for such activities with European companies remains significantly lower than for activities with US companies.

The EBC expects further agreements or Memoranda of Understandings (MOU) between the EU and Japan, similar to the MOU between METI-DGAC. The EBC also welcomes initiatives at company level, such as the cooperation agreement on composite material technologies signed in June 2009 between Airbus and the Japan Aerospace Exploration Agency (JAXA).

Recommendations:

- The EBC strongly believes in the mutual benefits of increased industrial cooperation between Japan and Europe, particularly in the field of commercial aircraft, engines, components, and navigation systems. New challenges lie ahead in the search for innovative solutions to meet future needs in the civil aviation sector. The EBC considers these challenges as an opportunity to enlarge the scope of cooperation between Japan and Europe and encourages METI and relevant government-affiliated institutions to openly promote and fund collaboration with European companies.
- Europe is supporting ambitious research programmes to tackle environmental issues, from noise to emissions. The EBC believes the environment to be one of the fields where further links between European and Japanese academia, technology clusters, and industry at large could yield significant cooperation and business opportunities, which should be examined further by both sides.
- The EBC would also welcome invitations from the Japanese aerospace industry for European companies to participate in domestic programmes or technology developments.
- EBC strongly recommends Japanese heavy industries to consider international joint development programmes for building aircraft or helicopters from scratch.

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SPACE

Introduction

After regaining power in December 2012, the Liberal Democratic Party upheld the reform of Japan's space jurisdiction initiated a decade ago and continued by the Democratic Party of Japan from 2009. The Space Policy Commission and the Office of National Space Policy established within the Cabinet office now set Japan's space policies across all Japan's ministries and agencies. A new "Basic Plan on Space Policy" was adopted in January 2013. Space is now regarded as an important industrial and commercial sector that is also critical for national security. Japan's high sovereign debt also contributed to making an effective unification of space policies a necessity. In an effort to maintain a healthy domestic space industry, Japan's administration actively seeks growth in export markets, although the industry is still mostly geared towards domestic government contracts.

The Ministry of Economy, Trade and Industry (METI) has been pro-actively helping all-Japanese industry consortia to supply complete satellite systems to emerging countries through Official Development Assistance (ODA) funding. Complete packages include satellites, launch services, operations, data analysis, maintenance, training, technology transfers, and other services. Contrary to EU policy, Japan's ODA contracts must be awarded to its domestic industry, resulting in a distorted market that excludes foreign manufacturers and service providers.

The EBC generally supports Japan's reform as it made its jurisdiction more consistent and intelligible. While generally respecting Japan's space policies, however, the EBC believes that fewer all-Japanese consortia, less tied ODA and more work with Europe would bring advantages in terms of budgetary savings, national security, research and development, and commercial success in the world. Although Japan has long ignored most European capabilities in the space area, we hope that the context of the current FTA negotiations will convince Japan to prove that its claims of an open market are credible.

The private satellite market is ostensibly open to all suppliers. There used to be at least one launch of a communications or a broadcasting satellite a year, but the market is now in a trough. Satellites with business and practical applications of former government monopolies have been procured through international tenders since 1990. These now only relate to the Multi-functional Transport Satellite (MTSAT) series and the broadcasting satellite (BSAT) series. Participation in government tenders is very difficult for European companies, due largely to the contract language, unlimited liability, other unrealistic clauses, and currency problems.

No-tender government programmes include the science and technology satellites of the Japan Aerospace Exploration Agency (JAXA), a small number of programmes under METI, and the defence-purpose remote-sensing Information Gathering Satellites (IGS). A dedicated defence communications satellite programme is underway. Japan's willingness to cooperate in satellite development programmes, however, still rarely extends to European companies.

Ariane launchers are successful in Japan and could play a broader role in cooperation. Arianespace and Mitsubishi Heavy Industries already allow commercial customers to shift satellites from Ariane 5 to H-IIA and vice-versa to avoid launch delays due to technical mishaps. However, talks between the Japanese and European space authorities towards a mutual back-up of government launch missions have stopped. In addition, legislation now under consideration may require Japanese commercial customers to seek government approval before procuring foreign satellites and launch services. Any need to apply and wait for government approval would hinder growth in this time-sensitive business.

Japanese investment in ground equipment has been spurred by its move into security and defence applications. Japan's space activities increasingly require ground equipment for image processing and interpretation, and for applications in agriculture, fisheries and geophysics. In addition, homeland security-type applications enhance defence capability. Protectionist procurement methods are still being used in this area to the disadvantage of foreign suppliers.

Key Issues and Recommendations

■ General environment

Yearly status report: wait and see. The Cabinet Office is now defining new, government-wide space policies. The political will to have all ministries and agencies comply with them will be put to the test. The EBC advocates unified policies that enable mutually beneficial trade and cooperation. More openness towards EU industry would benefit Japan, as Europe provides many technologies free from “black-box” technology concealment policies. Japan is testing Private Finance Initiative (PFI) procurement. A temptation is that satellites with both public and commercial purposes could be declared governmental as far as building and launching them is concerned. Foreign satellite makers and launchers could thus be excluded from Japan’s commercial market in a piecemeal fashion.

Recommendations:

- The EBC urges more Japanese cooperation with European space agencies. Space agencies on both sides should compare their projects at an early stage and take greater advantage of cooperation opportunities.
- Japan should also encourage more cooperation between the Japanese and European space industries.
- The EBC recommends mutual recognition of Japanese and European export control procedures.
- The EBC recommends Europe-Japan coordination and cooperation in space-related ODA worldwide.
- PFI projects should not exclude the participation of European companies.
- The EBC hopes that Japan's satellite communications and broadcasting industry will not be subjected to regulatory burdens, difficulties or delays when acquiring foreign satellites and launch services.

■ Satellites

Yearly status report: no progress. Japan mostly ignores Europe’s satellite technology. The space agencies of both sides cooperate and share data in science and research, but have almost no industrially meaningful cooperation.

Recommendations:

- The EBC advocates closer space agency cooperation in satellite technology development and applications, with pro-active promotion and execution of industrially and commercially meaningful cooperation projects.
- The Government of Japan should increase cooperation with Europe through the procurement of high-quality satellite systems or equipment in fields related to national security. This includes the joint development of high-quality sensors or their production by Japanese industry under licensing arrangements.
- Government procurement methods, terms and conditions should not put European makers at a disadvantage.

■ Launchers

Yearly status report: no progress. Contrary to the other major space powers, Europe and Japan do not have laws prohibiting the use of foreign launchers to launch their governmental satellites. This means that if requested to launch a foreign government’s satellite because that government has technical problems with its own launchers, they can comply with the request and return equivalent launch business to the other side in the future. The EBC believes that Europe and Japan should take this opportunity and formally enter into a balanced agreement to back up each other's government launches to reduce launch delays. A plan was successfully presented to Japan’s space authorities in 2002, but no agreement is in sight as political leadership is missing on this issue.

Recommendation:

- New government satellite programmes will require more timely launches. The EBC urges Japan to bring about effective, formal back-up cooperation between Japanese and European satellite launchers.

■ Ground equipment

Yearly status report: no progress. As Japan's international procurement activities in this area generally exclude entire systems and remain limited to subsystems and components, foreign suppliers are placed at a disadvantage.

Recommendation:

- Japan's international procurement of ground equipment should include whole systems. The procurement process for standard ground processing products should not place European suppliers at a disadvantage.

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DEFENCE & SECURITY

Introduction

Japan is the world's third largest economy and an important ally for the EU, US and NATO (North Atlantic Treaty Organization), sharing common values and interests in the Asia Pacific region and globally.

In December 2012, the Liberal Democratic Party (LDP) won the lower house elections and returned to government with a bold programme of economic revitalisation and diplomatic assertiveness. Short-term data indicate that the economic strategy, 'Abenomics', is having positive results. It is hoped that the short-term gains will continue for the long term. The LDP, on its return to power, also re-affirmed its relationship with the US and furthermore, Japan's reliance on the US to underwrite the security of Japan. However, the Government is also taking a more assertive stance towards its regional neighbours - especially China - and in addition has expressed a strong desire to play a more active role in world security, including discussion on the potential for collective defence.

The security environment surrounding Japan remains complex. China continues to actively assert its claims on the Senkaku Islands and this combined with North Korea's missile development and ability to launch such weapons constitute an uncertain environment. In addition, political tensions remain with the Republic of Korea (Takeshima islands) and Russia (Northern Island chain). Furthermore, January 2013 tragically introduced Japan to the impact of terrorism on its international workforce. Eight hundred foreign and Algerian staff at the Tigantourine gas facility in Amenas, Algeria, were taken hostage by an Islamic terrorist organisation. Forty of these hostages including ten Japanese nationals lost their life. This raises the question of how democratic nations can work together to protect their nationals working in foreign countries against terrorist threats

Japan realises that it must reach beyond the US if it is to play a greater role on the global stage and has started to broaden cooperation with other maritime powers, such as Australia and India. Significantly, the LDP has followed through on the goal of the previous ruling party, the Democratic Party of Japan (DPJ), to form stronger defence and security ties with Europe.

In December 2011, the DPJ announced revised guidelines for Overseas Transfer of Defence Equipment. These guidelines permit the overseas transfer of defence equipment under certain conditions, by allowing comprehensive exemption measures under the Three Principles on Arms Exports. The announcement of the revised guidelines was followed in April 2012 by a Joint Statement on the UK-Japan Defence relationship, agreed between Prime Minister Cameron and then Prime Minister Noda in an attempt to forge closer links between Japan and the UK. The UK-Japan relationship was formalised in July 2013 with the signing of a bilateral agreement for defence cooperation. The importance of this agreement between the two countries was underwritten at the Royal United Services Institute (RUSI)/Sasakawa Peace Foundation conference, which took place in Tokyo from September 30 to October 1, 2013 at which both Prime Minister Abe of Japan and Prince Andrew of the UK made keynote speeches.

It is anticipated that this first agreement with Europe in the field of Defence and Security will be followed in 2014 by a similar bilateral agreement between Japan and France as Prime Minister Abe and President Hollande discussed defence collaboration during the presidential visit to Japan in June 2013. Germany is also moving forward to promote cooperation ties in defence research and technology and equipment through industrial ties. The Japanese government has released throughout 2013, a series of clear messages that Japan cannot afford to develop all the defence capability it desires through its own defence budgets.

The EBC has welcomed these changes and the opportunity to meet representatives from the Ministry of Defence (MoD), Ministry of Foreign Affairs (MOFA), Ministry of Economy, Trade and Industry (METI) and the Defence Production Committee of the Japan Business Federation (*Nippon Keidanren*) to discuss the guidelines and explore the implications for EU-Japan industrial partnerships. A series of forums has continued through 2013, organised between METI and various European bodies including the EBC, GIFAS (Groupement des industries françaises aéronautiques et spatiales and ADS (Aerospace Defence Security) to push forward the industrial dialogue.

Key Issues and Recommendations

■ Procurement

Yearly status report: some progress. The EBC anticipates that the Japanese government's desire to move towards collaborative defence programmes with Europe and the progress in bilateral agreements with individual European nations will result in amendments to the defence equipment acquisition process and improvements in transparency of the decision-making. The EBC believes that the recommendations listed below will also benefit the Japanese industry as it prepares itself to enter the world of defence exports.

Recommendations:

- Japan should improve transparency towards foreign suppliers by making the Statement of Requirements (SOR) for procurement processes more widely available and placing more emphasis on life cycle costs (LCCs).
- The MoD should consider adopting NATO standards for the initial research and development phase of each defence project to strengthen competition and reduce development risks.
- The Government of Japan should repeal unlimited liability in the terms and conditions of public tenders, since this puts foreign bidders at a considerable disadvantage vis-à-vis Japanese contenders.
- The MoD should also implement a multiyear contract scheme for weapon acquisition in order to obtain the best conditions in terms of prices and local content from foreign manufacturers.

■ Industrial partnerships

Yearly status report: progress. During 2012 and 2013, a series of Japan-Europe Defence Forums, organised with the support of METI, European bodies (EBC, GIFAS and ADS) and the *Nippon Keidanren*, have encouraged a closer dialogue between the Japanese and European defence industries. The Japan-UK bilateral agreement and the future agreements with France and other European countries will provide the vehicles to encourage collaboration between the industries. Revitalisation of the Japanese defence industry may depend on the diversification of its alliances as well as on joining new development programmes for dual use technology. In this respect, the European defence and aerospace industry is offering a number of new opportunities for joint development.

Recommendations:

- Japan should work with EU countries to identify pilot projects for collaboration on joint requirements.
- Intellectual property rights must at all times be respected if partnerships are to be successful.
- For Japanese authorities in charge of industrial policy, public funding should be provided to support those technologies that address both civil as well as military markets.

■ Defence exports

Yearly status report: some progress. The European defence industry has a large share of the global defence market through both direct sales and cooperation with foreign governments and industries. European defence companies are eager to work with the Japanese defence industry to develop programmes that have a broader market application and are capable of export by the partnership. However there is a need for further relaxation in the Three Principles on Arms Export in order to define a 'white list' of countries to which Japan may agree to export.

Recommendation:

- The Japanese Government should develop a better defined defence export policy.

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CONSTRUCTION

Introduction

The positive trend in construction investment, which started in 2011 and continued in 2012, is expected to maintain pace in 2013 and onward to 2020. Public and private investments peaked in 1992 at 82 trillion yen and reached their lowest point in 2010 at 41 trillion yen, but are expected to increase again to 50 trillion yen by the end of fiscal year 2013 (April 2014). However, despite this positive trend, both industry and also recent economic research have identified a continuing decrease in the Japanese population with a decrease in the overall workforce, especially in the number of skilled construction workers, as limitations to this positive scenario. This has become very apparent during the reconstruction of the Tohoku area.

The situation where demand for skilled labour exceeds supply can only be expected to become more problematic closer to the build-up to the 2020 Tokyo Olympics. Public and private investment will increase to improve existing buildings as well as to construct new ones. This activity will not be limited to property, but will extend to infrastructure projects, which often compete for the very same workforce. Accordingly, it is critical that Japan seriously considers amending its immigration policy to let construction companies, foreign as well as domestic, make use of overseas skilled labour. The sudden increase in investment must be accompanied by extra inputs of human resources and technologies. Therefore, the EBC believes that, as part of a broader immigration policy, the Japanese Government should consider expanding opportunities for construction companies to hire internationally qualified trade labour (such as carpenters, plumbers, electricians, and plasterers), to ease the recruitment difficulties they face. We also propose that the Japanese Government increases public measures and encourages more efforts by the private sector to recruit and train young people in the skilled construction trades. Providing support to foreign as well as domestic companies to provide training would be one way of relieving unemployment among young people not in education, employment or training (NEETs) and ensuring a stable supply of skilled construction labour in the future.

Recently, some analysts have suggested that the property market decline is bottoming out; however such optimism is dependent upon stimulation of the overall economy and favourable property investment policies. Leveraging new technologies and project delivery methods will be critical to unlocking new growth potential. One such area is sustainability. Given that over 30% of the energy in Japan is consumed by commercial and residential buildings, a figure that continues to increase, the activities of the construction and property management industry will fall under close scrutiny, especially as Japan addresses long-term power supply issues. In particular, in the wake of the Tohoku disaster and the resulting energy shortages, suppliers, authorities, and individual consumers have shown a renewed focus on sustainability and energy efficiency.

Many regulatory initiatives are made at municipal level via the administrative guidance process. This places the local authorities in a difficult position when required to make fair and technically informed decisions on compliance. In some cases, decisions are made even though the local authorities lack the necessary knowledge to interpret the legislation correctly and sometimes do so without reference to international standards. It also makes it difficult even for domestic companies to keep track of all the relevant guidelines. Furthermore, much of the documentation is available only in the Japanese language. This reduces transparency and hampers access to information by European companies, making it difficult for them to recognise opportunities or deliver goods and/or services in compliance with the latest regulations, even if they have the relevant technical capacity. The EBC encourages the Japanese Government to treat the strengthening of policies geared towards sustainable practices as a high priority and advocates standardisation of regulations and application of global equivalencies and internationally recognised assessment techniques as an alternative to the current unhelpful mix of local and proprietary incentives or quasi-mandatory administrative guidance.

The EU-Japan FTA/EPA should include mutual acceptance of standards and certifications to enable construction product convergence, so that EN standards (European Standards) and CE-marking (*Conformité Européenne*) can be used interchangeably with JIS/JAS standards (Japan Industrial Standards/Japan Agricultural Standards). It should also ensure improved transparency, strictly enforced common rules for government procurement, and joint recognition of the role of construction in promoting a sustainable society.

Key Issues and Recommendations

■ Harmonisation of building material standards and contractor qualifications

Yearly status report: no progress. European firms could make a significant contribution to the development of Japan's construction market in terms of innovative designs, technology, materials and methods, but attracting them will require the reform of over-prescriptive regulations, and rationalisation of unnecessarily complicated procedures for obtaining mandatory approvals. Little progress has been made in aligning standards and testing methods across industries and across borders, so re-testing and re-certification are still required. Inevitably, this raises the cost of imports to Japan and makes them less competitive than domestic supplies.

Recommendations:

- The Japanese and EU authorities should work towards mutual recognition of JAS/JIS and EN standards for building materials and ensure this is covered in negotiations towards a comprehensive FTA/EPA. CE marking of construction products should suffice as a guarantee of their high quality and safety when sold in Japan. Non-harmonisation is still common, examples being in the flooring sector and for roofing sheets.
- The Japanese authorities should recognise relevant foreign experience as equivalent to domestic experience when granting a general construction licence (*kensetsugyo kyokasho*).

■ Promotion of environmentally friendly construction

Yearly status report: some progress. Improved building insulation is one of the simplest and most effective ways to reduce energy use, and also generates a positive monetary return. While Japan has now put regulations in place to drive higher performance from new buildings, emphasis must also be placed on improving the efficiency of existing building stock through incentives geared to stimulate the renovation market. Opportunities may span from simple component replacements, such as double-glazed windows, high-efficiency air conditioners or installation of insulation in walls and ceilings, to the application of new technologies for on-site energy recovery, water treatment and other conservation strategies.

Recommendations:

- The Government of Japan should continue to strengthen regulations aimed at promoting energy efficiency in residential and commercial buildings as a way to fulfil its international commitment to cut carbon emissions, with a view to applying the best available technologies in an integrated systems approach and transparent methods for measuring performance achievement.
- The Government of Japan should mandate the introduction of much stricter insulation standards for buildings. Rating tools such as CASBEE (Comprehensive Assessment System for Built Environment Efficiency), and schemes such as the Energy Efficiency Standard for Houses and the PAL/CEC (Perimeter Annual Load/Coefficient for Energy Consumption) assessment for larger office buildings, are heading in the right direction, but produce buildings that are not yet up to international standards.

■ Transparency and accessibility of information and regulations

Yearly status report: no progress. Currently much of the interpretation of national construction-related legislation and guidelines is left to the discretion of local authorities. This has created a situation of uncertainty with questionable decisions in some cases being made where local authorities lack the necessary knowledge to interpret the legislation correctly.

Recommendation:

- The competent national authorities should take appropriate action to rationalise the patchwork of local regulations that exists today and to further educate local authorities by clarifying the legal framework.

■ Immigration regulation

Yearly status report: new issue. Both the continuing reconstruction of the Tohoku region and future investments in the build-up to the Olympics will put strains on existing human resources within the construction sector. Japan should swiftly amend its immigration policy so that companies can recruit skilled labour from abroad.

Recommendation:

- The Japanese Government should liberalise its immigration policy so that construction companies can use overseas skilled labour on fixed-term contracts.

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MATERIALS

Introduction

Japan has developed vast knowledge and expertise in processing and recycling materials, and is at the forefront of many sensitive technologies, such as those used to produce rechargeable batteries for hybrid vehicles, nanotechnologies for manufacturing semiconductors, and various products related to environmental technology, among others. These advanced technologies depend on the availability of key raw materials and Japan's ability to secure a stable, high-quality supply. It is, therefore, of the utmost importance that Japan adopts a strategy based on security of supply at competitive prices, which can only be achieved by allowing overseas suppliers unrestricted access to its domestic market. A shift in strategy among Japanese companies has already taken place to minimise risk and dependency on unstable sources, leading them to diversify purchases despite existing tariffs. Ultimately, however, their competitiveness is compromised because these tariffs have to be passed on to their customers.

Japan, one of the main consumers of industrial materials in the world, would benefit greatly from better access to the reliable sources of high-quality products at market-based prices that European companies can offer. However, Japan has been reluctant to reduce tariffs on industrial materials on a unilateral basis before formal negotiations on tariff reductions are concluded under the auspices of the World Trade Organisation (WTO). With the breakdown of the Doha Round, Japan has started to reconsider this policy. The unilateral lifting of tariffs on high carbon ferro-chromium (tariff code 720241000), a key ingredient in the manufacturing of all stainless steels, was a welcome step of major importance.

Tariffs damage competitiveness and threaten the future of Japan's domestic industry. Tariffs on processed nickel significantly increase local procurement costs, at a time when companies in sectors such as stainless steel production are facing stiff challenges from overseas competitors, particularly in South Korea and China. The same situation applies to fused aluminium oxide (artificial corundum) and to silicon carbide, both of which are widely used in the refractory and abrasive industries and in electric components. Imported fused aluminium oxide and silicon carbide are both subject to a 3.3% tariff, even though domestic production can only fulfil, at best, 10% of annual demand.

Tariffs are not the only barrier to increasing the business potential between Europe and Japan. Non-tariff barriers in the form of administrative burdens, regional differences in registration procedures and inconsistent use of classifications make doing business in Japan unnecessarily costly and difficult for foreign companies. The benefits of eliminating tariffs and of harmonisation and simplification would be felt not only by European suppliers, but even more by Japanese industry, making it more competitive.

During manufacturing processes, waste products are generated and at the end of a product's life, a recycling process is usually initiated. The by-products from the metallurgical, smelting and refining industries as well as end-of-life products, whether from industrial or end-user origin, are stockpiled, dumped or recycled. Japan's Waste Management and Public Cleansing Law, enacted in 1970, addressed the importance of preserving and recycling materials to the maximum amount possible for the sake of protecting the living environment and saving resources. Japan took the lead in recycling and many countries have in the meantime followed its example. A global industry has developed and companies in Japan and Europe are now world leaders in this field. The law in Japan has, however, been very restrictive with respect to importing and exporting waste for recycling. While this may be understandable to prevent any "waste" from being exported or imported for unethical or environmentally unfriendly processing, it has also hindered Japanese companies seeking the environmentally sound recycling schemes offered by European recycling companies. The EBC advocates that free movement be allowed as long as it complies with international laws (such as the Basel convention) and that best available technology is applied, even if this means that goods are exported with a negative value. Under current legislation, the conditions for export are too restrictive.

The EBC believes that the EU-Japan FTA/EPA should address these issues by including the removal of tariffs on all material related products, both raw materials as well as processed products.

Key Issues and Recommendations

■ Tariff issues

Yearly status report: no progress. Currently, Japan retains tariffs on some metals. These metals are in many cases essential for Japan's core industries including the vehicle, battery and more traditional steel industry. The tariffs constrain the competitiveness of Japanese manufacturing, a sector already under pressure from low-cost countries. Removal of import tariffs is, therefore, imperative for Japan to retain its competitive edge. For the stainless steel industry, where 40% of the production cost lies in the cost of nickel, the tariff plays a major role. The same can be said for the battery and photovoltaic sectors, where it makes little sense to penalise companies with an additional cost added through a tariff. The EBC believes that further investment could be made in these sectors if input materials could be imported duty-free. This is of particular concern for silicon carbide and manganous manganic oxide as domestic production of these goods accounts for only 10% of the demand. Supplies of industrial materials to Japan are occasionally subjected to arbitrary tariff classifications and revisions. Regional Customs offices do not apply classification rules on a consistent basis and the appeal mechanism is both time-consuming and costly, without any guarantee that the outcome will be in line with international practice. This is a problem not only for products entering the market for the first time, but also for well-established products subject to sudden classification reviews.

Recommendations:

- Under the EU-Japan FTA/EPA, the Government of Japan should remove import tariffs from all industrial raw materials, including:
 - ◇ nickel products and aluminium, such as semi-fabricated and flat-rolled aluminium,
 - ◇ fused aluminium oxide, silicon carbide, and manganous manganic oxide, and
 - ◇ non-organic chemicals and polymers.
- The Government of Japan should rationalise its tariff classification regime and develop a comprehensive strategy to improve consistency between regional Customs offices in classification rulings, and to strengthen and simplify dispute resolution mechanisms.

■ Chemical Substance Control Law

Yearly status report: some progress. With both the EU and Japan now having introduced chemical substance registration systems, producers, exporters and importers are faced with re-testing, double submissions and an increased administrative burden to fulfil the respective regulations. On top of this, the EBC is also concerned that in some cases in Japan, sensitive confidential information has to be handed over to competitors, in order for a product to be tested and approved. This gives an unfair advantage to the competitor, upsets the level playing field and creates unbalanced competition.

Recommendation:

- Japan and the EU should harmonise their registration systems or mutually recognise test results and supporting documents to avoid re-testing and unnecessary administrative burdens.

■ Waste Management and Public Cleansing Law

Yearly status report: new issue. The EBC believes the very stringent restrictions of the Waste Management and Public Cleansing Law that limit import and export of waste products for recycling purposes (by-products, industrial waste and end-of-life products) should be abolished to allow for free movement and trade of these products. This should be allowed irrespective of their value on the condition that international trans-border conventions are respected and good practices (environmental and ethical) are applied. In order to ensure proper handling, the EBC envisages an efficient and non-time consuming approval process.

Recommendation:

- Japan should apply international conventions to the import and export of waste products for recycling purposes and abolish its current restrictions on this trade.

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ENERGY

Introduction

The Japanese utility industry is run by ten regional private power companies that have a virtual monopoly on power generation, transmission and distribution in each area. In March 2000, partial liberalisation of the power retail supply for extra high voltage users was introduced. The Electricity Industry Committee, an Advisory Committee for Natural Resources and Energy, a consultative body to the Ministry of Economy, Trade and Industry (METI), decided upon a limited model of liberalisation, where the vertical integration of generation, transmission and distribution was maintained in order to secure a stable supply of electricity. In the area of price setting, the “cost+” model, which was already in use before the partial liberalisation, has been reviewed various times, but has remained intact ever since.

Japan is highly dependent upon imports for gas, oil and coal. Following the oil crisis of the 1970s, Japan set out to reduce this dependency through increased use of nuclear energy. The 2010 power generation energy mix consisted of: 26% nuclear, 11% renewables, 57% fossil fuel and 6% combined heat and power. However, after the March 2011 Tohoku disaster and related Fukushima nuclear accident, Japan’s nuclear plants were shut down and, as of 2013, most are still not operating. With only Kansai’s Ohi No. 3 and No. 4 reactors online, nuclear power accounted for less than 2% of Japan’s total electricity generation in FY2012. Accordingly, Japan’s dependence on imported fossil energy resources has increased again.

Japan’s energy policy is enacted in the Basic Act on Energy Policy, which sets the following goals:

1. Securing of a stable energy supply
2. Environmental sustainability
3. Use of market mechanisms, which should, however, remain consistent with the first two basic goals.

After the March 2011 nuclear disaster, Japan’s utility model was placed under review. A METI committee on industry reform proposed splitting off power generation from transmission operations and creating a nationwide entity to manage major power lines. Currently, Japan’s transmission network is centred around the production sites, with the main transmission at 500kV. Three convertor stations connect the 50Hz and 60Hz networks. European and US grids are based on the mesh concept with extensive plans on use of High Voltage Direct Current (HVDC), which means more flexibility in energy flows from one region to another and easy integration of non-conventional energy sources in the overall energy sum.

Besides the overall model, the energy mix was and continues to be reviewed. The current LDP-Government decided that “the former DPJ-administration’s policy of abandoning nuclear power had to be reconsidered to help revive the economy”. It has said, in particular, that it plans to spend up to 10 years in determining the most appropriate future energy mix. METI’s Advisory Committee for Natural Resources & Energy aims to compile a Basic Plan before the end of 2013.

In July 2012, the new Feed-In Tariff (FIT) scheme for renewable energy sources came into effect, requiring the utilities to buy power derived from solar, wind, geothermal, hydropower and biomass sources at a fixed tariff and allowing them to pass on the cost to consumers. The aim is to further promote investment in the renewable energy field as part of the “Green Growth Strategy” laid out by the Government’s Energy and Environment Council. As a result more than 1,662 MW of installed renewable capacities started operating between April 2012 and February 2013, amounting to 1.6% of total energy generated in FY2012.

The EBC expects energy to be discussed in the FTA/EPA negotiations in order to further strengthen the ties between Japan and the EU in this area, where there is so much that we could learn from each other.

Key Issues and Recommendations

■ **Stability of supply versus cost**

Yearly status update: some progress. Stability of supply must remain the first priority for the Japanese economy. However, the “cost+” model may not be providing adequate incentives to the utility companies to reduce costs and increase efficiency. Fossil fuels are and will most likely remain the key pillars of the energy mix, but their costs are currently unsustainable and will remain so in the short-term for Japanese utilities, thereby affecting the competitiveness of Japanese industry in general in the global market. The current yen exchange rate is further affecting the increasing cost of fuel imports.

Recommendations:

- The utility companies should accept international standard products and solutions, which can drastically reduce both Capital Expenditure (CAPEX) and Operational Expenditure (OPEX).
- Transparency in procurement should be increased in line with the World Trade Organisation’s guidelines.
- Among the fossil fuels, the use of natural gas should be increased and gas-fired thermal power plants should be preferred for future investments in power generation, in order to reduce greenhouse gases.
- Nuclear energy could also remain a core constituent of the Japanese energy mix, as it plays an important role in providing industry and citizens with competitively priced electricity. Its long-term sustainability depends on clear confirmation of the closed fuel cycle policy (waste volume reduction, storage and re-use). However, it would be necessary to deal with the ageing of existing plants, improve facility utilisation rates, and properly manage the nuclear fuel cycle.
- The development of renewable energies must be carried out with ambitious, albeit realistic targets, aiming at increasing the safety and reliability of the energy supply. Achieving grid parity is essential; however it must not be pursued to the detriment of industry competitiveness.

■ **Separation of generation, transmission and distribution**

Yearly status update: some progress. The current situation does not provide the transparency and cost efficiency required. Security of supply is also not guaranteed, with limited interconnections between utility companies as well as between the 50Hz and 60Hz networks.

Recommendations:

- Separate ownership of generation from transmission to allow the required investments in the transmission grid, while providing transparency and efficiency in terms of cost.
- Establish a national grid planning body overseeing the need for energy on a countrywide basis.
- Use the latest international High Voltage Direct Current (HVDC) solutions to create new flexible bi-directional power flow corridors. This approach would enable the use of the existing right of ways and sub-sea connections and increase capacity to integrate renewable energy sources more efficiently.
- Strengthen the 50-60 Hz connection using HVDC.
- Use the latest Flexible Alternate Current Transmission System (FACTS) with energy storage options to strengthen the transmission grid.

■ **Nuclear energy & nuclear safety**

Yearly status update: some progress. In the wake of the Fukushima nuclear accident, Japan has reformed its nuclear safety regulator, which is now an entity with enhanced independence. Since it was established in September 2012, the NRA (Nuclear Regulatory Authority) has worked on new nuclear safety standards and nuclear safety regulations, which were published and enforced in July 2013. The new standards bring major changes and new rules compared to before the Fukushima nuclear accident. Based on these new safety standards, the NRA will check the safety of all Japanese reactors, and confirm whether they can be restarted or not. As of September 2013, four utilities had applied to the NRA for safety inspections for a total of 12 reactors. The EBC believes it is of the utmost importance for the new safety rules issued by the newly created NRA in July 2013 to be properly implemented by the Japanese power utilities.

Recommendations:

- Continuously increase the level of safety of nuclear energy under the scrutiny of an independent regulatory committee such as the recently created NRA, consisting, among others, of nuclear energy experts.
- Review safety measures at individual plants with support from international inspectors and implement recommendations before any restart.
- Use international standards and procedures as minimum requirements, such as the asset and operation management system used in Germany and France.
- Share best practices and establish common safety requirements through international cooperation.
- Develop a practical working system to deal with nuclear waste treatment and storage, which are still pending issues.

■ Wind energy

Yearly status update: no progress. Wind energy is a proven way for Japan to reduce its reliance on imported fossil fuels, and to make use of one of its own local energy sources. Furthermore it could help Japan reach its emissions targets without the pollution or safety risks of many other fuel sources. It is, therefore, unfortunate that Japan still does not properly promote the use of on-shore as well as off-shore wind farms. Modern wind turbines now contain sophisticated technology that works well with established power grids of all kinds, such as large transmission systems or isolated local grids. The EBC recommends that the Japanese Government takes note of the work on technical standards for wind energy being carried out by the International Electrotechnical Commission (IEC).

Recommendations:

- Reduce the number of unnecessary regulations that add to the cost of wind farm development, a cost that ultimately is paid by the Japanese population.
- Revise environmental impact assessment requirements applicable to wind farm development to a more appropriate level that enables wind farm development within a reasonable time frame.
- Adopt internationally accepted certification standards for wind turbines and their componentry as technical requirements rather than existing local certification laws/regulations. This is vital both to facilitate increased investment and improve the potential for Japanese technology exports.

■ Solar energy

Yearly status update: some progress. Principal impediments to sustainable growth of utility and commercial-grade solar energy are: the cumbersome procedure for obtaining special permits for land re-zoning for non-agricultural uses; sourcing engineering and construction firms with the potential to acquire financing; and obtaining project financing for mega-PV (photovoltaic) projects. Additional challenges that Japanese utility companies may soon encounter are managing cost effective solutions to integrate decentralised and intermittent renewable generations into the existing power grid.

Recommendations:

- Streamline the process to re-classify special permitted lands for renewable power generation.
- Adopt internationally accepted certification standards for solar modules and system components rather than enforcing existing “Japan-only” certification standards.
- Adopt an accreditation scheme to support the acceptance of test results, reports and certificates from any accredited certification body, both domestic and foreign.
- Increase Government support to drive the adoption of standard criteria for Japan’s megabanks and regional banks to provide debt financing.
- Create incentive programmes for the power utilities to contract PV project construction to an emerging class of Japanese engineering and design companies.

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